SCHOOL-BASED, VOLUNTARY HPV VACCINATION: WHAT CAN TEXAS LEARN FROM AUSTRALIA?

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ABSTRACT

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Title: School-Based, Voluntary HPV Vaccination: What Can Texas Learn from Australia?

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While a vaccine has been developed that protects against the majority of cancer-causing HPV strains, vaccination rates remain low in the United States. Nationwide, vaccination completion rates are unlikely to reach goals set by the Office of Disease Prevention and Health Promotion's Healthy People 2020 initiative. Further, rates in Texas lag behind national averages. Australia has high HPV vaccination rates, due in part to their successful school-based vaccination program. Using archival research, I will identify approaches used in Australia's school-based vaccination program that could be applied to programs in Texas. Data obtained from phone interviews with two researchers implementing school-based HPV in Texas: Dr. Ana Rodriguez in the Rio Grande Valley and Dr. Paula Cuccaro in Houston, will be used as case studies. I will assess barriers and catalysts reported by the programs and use these findings along with suggestions from Australia to improve school-based vaccination programs in Texas.

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Chapter 1: Background

Cervical Cancer and the Human Papillomavirus

Cervical cancer is the cause of 266,000 deaths annually worldwide and is the fourth most common cancer among women in the United States (Pfaendler et al. 2). Although screening methods like Pap smears and improved treatment options have drastically decreased rates of death from cervical cancer, treatment can have negative impacts on patients' quality-of-life measures (*NIH Fact Sheets - Cervical Cancer*). Treatments for cervical cancer often include surgery and other invasive procedures in attempts to remove cancerous cells. Among cervical cancer survivors, side effects of treatment include bladder and bowel dysfunction, sexual dysfunction, lymphedema, and neurologic side effects (Pfaendler et al. 2).

Researchers long suspected that cervical cancer could have a sexually transmitted cause, but it was not until the 1980s that human papillomavirus (HPV) was identified as the cause of most cases of cervical cancer (*NIH Fact Sheets - Cervical Cancer*). HPV is the most common sexually transmitted disease and while most people are able to clear the infection within two years, HPV persists in some patients and can lead to poor health outcomes (*Basic Information about HPV and Cancer | CDC*). HPV is sorted into two categories: low-risk strains and high-risk strains. Low-risk strains cause genital warts, while high-risk strains can cause certain cancers (*Basic Information about HPV and Cancer | CDC*). Two high-risk strains, HPV-16 and HPV-18, cause seventy percent of all cervical cancers (*Cervical Cancer Causes, Diagnosis and Symptoms : NCCC*). There is a vaccine that protects against the two high-risk strains, as well as some low-risk strains. In addition to cervical cancer, the vaccine is also recommended to prevent oropharyngeal, vulvar, vaginal, penile, and anal cancer (Rodriguez et al. 592). The HPV vaccine

also protects against strains responsible for ninety percent of genital warts: HPV-6 and HPV-11 (*NIH Fact Sheets - Cervical Cancer*).

The HPV Vaccine

The HPV vaccine works by introducing the body to virus-like particles that have coat proteins in common with the HPV virus ("Human Papillomavirus (HPV) Vaccines"). The vaccine does not contain HPV DNA; instead, it mimics the virus so that the body can produce antibodies to mount an immune response against HPV ("Human Papillomavirus (HPV) Vaccines"). This means that when the body encounters HPV in the future, these antibodies will bind to the HPV virus, preventing it from infecting host cells ("Human Papillomavirus (HPV) Vaccines").

HPV vaccination can begin in children as young as nine years old, but the Advisory Committee on Immunization Practices recommends initial immunization at age eleven or twelve with catch-up doses through age 26 (Meites et al. 698). The vaccine cannot cure an existing HPV infection and is, therefore, most effective at preventing cancers if administered prior to sexual debut (Meites et al. 698). The vaccine is FDA-approved for people aged 9-45 years old; however, the AICP does not currently recommend catch-up doses in adults 27 and older (Meites et al. 698). This is because the benefit of vaccination would likely be minimal due to prior infections, although a catch-up vaccine in older patients may be appropriate in some circumstances to protect them from HPV (Meites et al. 698).

As of 2016, the Advisory Committee on Immunization practices recommends a two-dose sequence for adolescents that initiate the HPV vaccination sequence between the ages of nine and fourteen and a three-dose catch-up sequence for patients aged fifteen-years-old to twenty-

six-years-old (Meites et al. 698). The nine-valent HPV vaccine protects against many strains of HPV and the dose recommendations depend on the age of vaccine initiation (see table 1).

Table 1: Current HPV Vaccination Recommendations for 9vHPV, Gardasil 9 (Meites et al. 700)

Strains Protected Against	**Ages 9-14**	**Ages 15-26**	**Ages 27-45**
Types 6, 11, 16, 18, 31, 33, 45, 52, 58	Two doses Interval: 0, 6-12 months	Three doses Interval: 0, 1-2, 6 months	Three Doses Vaccination is safe, but not recommended by the AICP as it may not be effective if the patient has had previous infections. Interval: 0, 1-2, 6 months

Efforts to Mandate HPV Vaccination in Texas: Political Controversy

The unique political history of the vaccine in Texas also has led to controversy. In 2007, then-Governor Rick Perry attempted to require vaccination of all sixth-grade girls in Texas through executive order (Goodwyn). Perry received backlash from others in the Republican party and shocked Democrats. Perry's conservative Christian supporters were outraged that he would call for young girls to be vaccinated against a sexually transmitted infection. Others thought that Perry was undermining parent choice in requiring the vaccine. It was discovered that Rick Perry's Chief of Staff, Mark Toomey, was a paid lobbyist for Merck, the HPV vaccine manufacturer. They gave him several hundred thousand dollars to lobby on their behalf and also contributed to Perry's campaign (Goodwyn). Later that year, the executive order was vetoed by both Democrats and Republicans in the Texas Legislature (Goodwyn). As a result of this incident, some parents could believe that the approval and promotion of the HPV vaccine is connected to political wrongdoing and therefore question the safety of the vaccine (Goodwyn).

The Texas Cancer Plan Other Elements of HPV Vaccine Controversy in Texas

The HPV vaccine has been recommended in the United States for girls since 2006 and for boys since 2011 (Victory et al. 1678). Despite this, vaccination rates are still suboptimal, especially in Texas. The National Immunization Survey, conducted by the CDC, found that the HPV vaccination completion rate for American teens is around 51% overall as of 2018 ("National Immunization Survey-Teen 2018, Texas"). Texas lags behind the national average, with vaccination completion rates among thirteen to seventeen-year-olds at 43.5% ("National Immunization Survey-Teen 2018, Texas"). Males in Texas have an especially low HPV vaccine completion rate (see table 2).

Table 2: HPV Vaccination Rates by Gender in 2018, Texas and U.S. Compared To Goals

HPV Vaccination Rates by Gender in 2018, Texas and U.S. ("National Immunization Survey-Teen 2018, Texas")					**Goal for Vaccination Completion Rates**
	Female, ≥ 1 Dose	**Female Completion**	**Male, ≥ 1 Dose**	**Male Completion**	
United States	69.9%	53.7%	66.3%	48.7%	Healthy People 2020: 80% ("2020 Topics & Objectives: Immunization and Infectious Diseases")
Texas	64.6%	47.8%	55.5%	39.4%	Texas Cancer Plan: 60% female, 45% male by 2024 ("Texas Cancer Plan" 35)

These low vaccination rates have dire consequences. Texas ranks fourth in the United States (including D.C.) for cervical cancer incidence, with 9.2 out of every 100,000 Texas women developing cervical cancer in their lifetime, compared to a national rate of 7.6 out of

every 100,000 women ("Texas Cancer Registry Cervical Cancer"). Further, some regions are even more impacted: cervical cancer mortality is 30% higher in the Rio Grande Valley when compared to non-border counties in Texas (K. Boom et al. 199).

In order to address cancer rates, the state of Texas tasks the Cancer Prevention and Research Institute of Texas (CPRIT) with creating the Texas Cancer Plan to identify ways to lower cancer rates. The 2018 Texas Cancer Plan aims to reduce cervical cancer incidence through increasing HPV vaccination completion rates. They have created targets of 60% HPV vaccine completion for females and 45% HPV vaccine completion for males by 2023 ("Texas Cancer Plan" 35). CPRIT aims to promote policies that have the potential to increase HPV vaccination rates and reduce costs for HPV vaccination, educate healthcare professionals about the importance of the HPV vaccine, and create a reminder system for HPV vaccines (*Texas Cancer Plan — Cancer Prevention and Research Institute of Texas*).

Nationally, the CDC has goals to improve vaccination rates through the Healthy People 2020 Initiative. As a part of this initiative in 2010, the CDC outlined a goal of 80% HPV vaccination for adolescents aged 13 to 15 years old (*Immunization and Infectious Diseases | Healthy People 2020*). As HPV vaccination rates in Texas low (39.4% completion for boys, 47.8% completion for girls according to NIS-Teen 2018), it is unlikely that the 80% goal will be met by the end of the decade (*Immunization and Infectious Diseases | Healthy People 2020*).

Reasons for Low HPV Vaccination Rates in Texas

The literature shows that concerns about effects on sexual behavior, the recommended age of vaccination, and the safety of vaccination overall may lead parents to be hesitant about vaccinating their children against HPV. Concerns that HPV vaccination will increase risky

sexual behavior have been shown to be unfounded. Madhivanan et al. conducted a literature review of surveys measuring sexual behaviors of females aged 9-40 years old and their HPV vaccination status. They analyzed HPV vaccination data and contraception use, age of sexual debut, risky sexual behavior, number of sexual partners, pregnancy terminations, HIV incidence, and rates of sexually transmitted infections. In many cases, there was no significant connection found between HPV vaccination and the outcomes measured (Madhivanan et al. 379). Notably, HPV vaccination was correlated with a significant increase in some safer sex practices such as condom use (Madhivanan et al. 381). Even though this meta-analysis provides evidence that HPV vaccination does not increase risky sexual behaviors, parents may still hold this belief.

Another factor leading to low HPV vaccine uptake is parental concern over the recommended age of vaccination (Intlekofer et al. 41). The vaccine is most effective if it is administered prior to sexual debut (Meites et al. 700). Some parents have pushed back against vaccinating their children against sexually transmitted diseases at a young age (Intlekofer et al. 41). Parents may not feel the need to vaccinate their children if they do not perceive their child to be at risk for contracting HPV. Additionally, some parents of young boys may not see a direct benefit to the vaccine, as their sons are not at risk for developing cervical cancer, even though they are still at-risk for other HPV-related cancers that parents may not be aware of (Holman et al. 78).

An additional concern is the safety of the HPV vaccine and vaccines in general (Intlekofer et al. 39). Adverse vaccine effects in the U.S. are reported to the Vaccine Adverse Event Reporting System (VAERS), which is managed by the CDC and FDA ("The Vaccine Adverse Event Reporting System (VAERS) Results Form"). In the case of HPV, the vaccine has been found to be very safe. The most common side effects are pain and swelling at the injection

site (Intlekofer et al. 40). However, there are unsubstantiated claims that the vaccine can be seriously harmful. For example, former United States Representative Michele Bachmann once claimed that the vaccine was linked to mental retardation; however, these claims are unfounded (Intlekofer et al. 39).

School-based Vaccination Programs

Providing parent education that emphasizes the benefits of HPV vaccination while disproving these misconceptions about the HPV vaccine being dangerous may help to increase HPV vaccination rates (Rodriguez et al. 599). Many programs aimed at increasing HPV vaccination have an education component. One intervention that pairs vaccine education with vaccination is school-based vaccination programs.

School-based vaccination is not a new idea. In the United States, children were vaccinated in schools in 1875 for smallpox, in the 1950s for polio, in 1969 for rubella, in the 1990s for hepatitis B, and in 2009 against H1N1 and varicella (*School-Located Vaccination - National Association of School Nurses*). Today, school-based vaccination involves compiling and sending home consent forms based off of vaccination records. Then, teams of vaccine administrators come to schools to deliver the vaccines on a specific day.

Some countries like Australia have expanded school-based vaccination because it removes some barriers that parents face when vaccinating their children (i.e. finding a place to get vaccinated, scheduling visits for multiple doses, etc.) (Holman et al. 80). In addition, school-based vaccination is efficient; many children can get vaccinated in a short period of time (Perman et al. 5). In vaccines that require multiple doses, such as the HPV vaccine, school-based

vaccination can ensure that children receive all the necessary doses and at the correct times; parents do not have to schedule appointments with their general practitioner (Rand et al. 462).

Perman et al. conducted a literature review that compared and contrasted current school-based clinics in high-income countries. They found several factors in common across many school-based vaccination clinics. School-based vaccination clinics provide vaccinations on-site that are administered by school nurses, health department staff, or other vaccination providers. In addition to providing the vaccine, these clinics often include education on the provided vaccine for parents and allow for vaccination tracking status within the school (Perman et al. 5). Programs can also include education for school nurses and staff as well as healthcare providers in the community. Consequently, school-based vaccination clinics have the potential to have positive impacts on vaccination rates in the greater community, outside of the patients that they vaccinate (Perman et al. 3). In the case of the HPV vaccine and other vaccines that require multiple doses, these clinics can help with scheduling doses over several months.

In the U.S., the most common school-based programs are for seasonal flu vaccines rather than the HPV vaccine (Perman et al. 1). However, some countries provide many more immunizations in school-based settings. Australia in particular has a very robust school-based vaccination program. There, all recommended childhood vaccines are a part of the National Immunisation Program and are given in schools ("History of Immunisation in Australia"). As a part of the program, the HPV vaccine is administered to children in grades 7 or 8 of school in Australia (approximately 12-13-year-olds) (Ward et al. E172). This program had led to large increases in HPV vaccination rates In Australia ("Historical Human Papillomavirus (HPV) Immunisation Coverage Rates"). While the U.S. does not have an existing national school-based

program like Australia, there are ongoing research projects in Texas that are hosting HPV vaccination clinics at schools.

Thesis Objectives

In my thesis, I will conduct archival case study research on current successful HPV vaccination projects and determine how they could be applied to Texas. Namely, I will examine Australia's school-based vaccination program which has successfully increased vaccination rates since its induction in 2006 ("Historical Human Papillomavirus (HPV) Immunisation Coverage Rates"). Despite differing healthcare systems, it may be advantageous for Texas programs to be modeled after Australia's program.

In this thesis, I will examine the social, cultural, and political barriers to implementing voluntary, school-based vaccination programs in Texas. I will cover the following questions in my archival research:

1. How would ideal school-based vaccination programs in Texas be carried out?
2. Would Texas parents be open to school-based HPV vaccination?
3. What steps would need to be taken in order to have schools host vaccinations?
4. What other changes could be made to facilitate school-based HPV vaccination?

Methodology

In order to investigate these questions, I will rely on a combination of archival research and interviews from experts conducting research in the field. By contacting and interviewing researchers (Dr. Paula Cuccaro and Dr. Ana Rodriguez) currently trying to implement school-

based vaccination for HPV in Texas, I will investigate the barriers they face when trying to create and run these programs.

My two case studies will be Dr. Cuccaro's program in Houston, and Dr. Rodriguez's program in the Rio Grande Valley. First, I conducted archival research on Dr. Rodriguez and Dr. Cuccaro's projects. This was a combination of papers from databases written about the projects and data obtained from the researchers themselves. Dr. Rodriguez conducted a meta-analysis of school-based HPV vaccination programs before starting her project, and I used this as a starting point for my research as well (Rodriguez et al.). There was also a paper published on the results of her first school-based HPV vaccination intervention from 2016-2018 that I used for assessing the changes in vaccination rates (Kaul et al.). For Dr. Cuccaro's project, I relied on data relating to refusal rates, vaccine uptake, and initiation and completion rates for HPV vaccination that was given directly to me by Dr. Cuccaro and the project lead Efrat Gabay. I also conducted phone interviews with them, where I inquired about the structure of their programs as well as the barriers they have faced in implementing their programs. The phone interviews were 35-40 minutes long and recorded so that they could be transcribed later. I also took limited notes during and after the interviews.

My third case study will examine the Australian school-based vaccination program. I will use archival research to deduce how Australia's barriers compare to Texas' barriers and how to best overcome them. Archival data was found through the University of Texas Libraries database. Search terms included "school-based HPV vaccination," "school-based HPV vaccination + 'Texas,'" "school-based HPV vaccination + 'Australia,'" etc. I also looked at the works cited for each paper to ensure that I did not miss prior research. Ultimately, my findings

will be used to determine what successful approaches can be applied to current efforts in Texas, as well as how current Texas programs can be improved upon.

Australia's School-Based HPV Vaccination Program

Victoria's *Public Health and Wellbeing Act 2008* (formerly known as *Health Amendment Act 1990*) mandates that children living or going to school in a certain municipal district are entitled to vaccination services by their council, including for the HPV vaccine ("School Immunisation Guides and Agreement" 7). Councils are responsible for coordinating school-based vaccination ("School Immunisation Guides and Agreement" 7). The National Immunisation Program (NIS) launched in 1997 and implemented a "Seven-Point Plan" including school-based vaccination in order to increase vaccination rates (see table 3) ("History of Immunisation in Australia").

Table 3: NIS "Seven Point Plan" to Increase Vaccination Rates ("History of Immunisation in Australia")
1. Parental incentives 2. Incentives for general practitioners 3. Creating and monitoring immunization targets 4. Immunisation events in schools 5. Measles elimination 6. Establishment the National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS) for research on vaccines

7. Require vaccines for school entry

One remarkable element of Australia's HPV vaccination rate successes is that their school-based program is voluntary In Australian schools, parents fill out forms affirming that they consent to their children getting the HPV vaccine along with several other age-appropriate vaccines ("National Immunisation Program Schedule"). This program is government-mandated The HPV vaccine is administered in either grade 7 or 8 (approximately ages 12-13), depending on the state and territory. The program also provides schools with educational resources to share with parents and students. On vaccination day, nurses come to the school and administer vaccines for each grade level. Table 4 details HPV vaccine initiation and completion rates in Australia.

Table 4: 3-Dose HPV Vaccination Coverage for Children Turning 15 in 2017, Australia ("Historical Human Papillomavirus (HPV) Immunisation Coverage Rates")

	Dose 1	Dose 2	Dose 3
Female	88.9%	86.0%	80.2%
Male	85.0%	81.9%	75.9%

The data reported above is from a time period when three HPV vaccine doses were recommended. The rates of vaccination sequence completion are expected to increase with the newer recommendation of two shots for children that start the vaccine sequence under the age of 15 (Brotherton et al. 262). The Australian Cancer Council cites unreturned consent forms (either to logistical issues or low awareness of the importance of the HPV vaccine) and vaccination day

experience as reasons why the vaccination rate hovers around eighty percent and is not higher ("National Immunisation Program Schedule").

International Differences in School-Based Vaccination

School-based vaccination differs between Australia and Texas in several key ways, including staffing, funding, and billing. In Australia, school-based vaccination programs are run by local health departments Conversely, in the United States (U.S.), some programs involve multiple schools' nurses collaborating to run a program jointly (Perman et al. 6). If nurses are shared, schools may require additional funding in order to staff school-based vaccination clinics. There are also programs in the U.S. where schools partner with nonprofits, private healthcare providers, and volunteers for support (Perman et al. 5).

Another major problem in American school-based vaccination programs is the lack of centralized funding. There are three main ways to fund school-based vaccination programs: the local health department, industry grants, and federal grants (Limper et al. 807). Additionally, schools vary in their ability to host school-based vaccination programs. This leads to major discrepancies in program feasibility; some schools have their own full-time nurses, while others share nurses within school districts (Limper et al. 806). In contrast, Australia's government-funded program employs teams of vaccine providers that travel to schools to set up the vaccination clinic in cafeterias, libraries, or classrooms ("Vaccination Videos for High School Students").

Billing for services is also more complicated in the United States. Australia's school-based program does not have major funding barriers because all citizens and permanent residents of Australia and New Zealand are eligible for Medicare ("What Is Medicare?"). This program

provides recommended vaccinations to children for free under the National Immunisation Program ("National Immunisation Program Schedule"). In contrast, people in the U.S. pay for vaccines through a mix of private insurance, out-of-pocket costs, and public programs. Uninsured or underinsured children, CHIP recipients (low-cost health insurance children who are low-income but who do not qualify for Medicaid), children on Medicaid, and children who are Native American or Native Alaskan qualify for free or reduced vaccines through the Texas Vaccines for Children program (*Information for Providers - Texas Vaccines for Children*). This is a state-specific offshoot of the federal Vaccines for Children program.

Therefore, school-based clinics in the U.S. must navigate billing for private insurance and Medicare, as well as the uninsured. Healthcare systems differ by country and are a large factor in determining how healthcare services are paid for. Healthcare system types for the U.S. and Australia are summarized in table 5.

Table 5: United States and Australia Healthcare Systems

Country/ State	Healthcare System	Population as of 2018 (rounded to nearest million)	≥ 1 Dose HPV, Females	≥ 1 Dose HPV, Males
Texas	• State-managed Medicaid for low-income people[1] • Single-payer Medicare for people over 65[1] • Private insurance, generally through an employer[1] • Nearly 5 million uninsured people in Texas[1]	US: 327 million[3] Texas: 29 million[3]	64.6%[4]	55.5%[4]

Australia	• Free inpatient care in public hospitals[2] • Voluntary private insurance[2] • Government pays for 85% of outpatient services, 75% for patients with private insurance that use public hospitals[2]	25 million[3]	88.9% (Children Turning 15 in 2017)[5]	85.0% (Children Turning 15 in 2017)[5]

[1]"Health Insurance Coverage in the United States: 2018." *The United States Census Bureau*. *www.census.gov*, https://www.census.gov/library/publications/2019/demo/p60-267.html. Accessed 17 Apr. 2020.
[2]Biggs, Amanda. "Medicare: A Quick Guide." *Parliament of Australia*, 12 July 2016, https://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/rp/rp1617/Quick_Guides/Medicare. Australia.
[3]*Current Population*. https://www.census.gov/popclock/print.php?component=counter. Accessed 30 Nov. 2019.
[4]"National Immunization Survey-Teen 2018, Texas." *Texas Department of State Health Services*, https://www.dshs.texas.gov/immunize/coverage/NIS/National-Immunization-Survey-Teen-(NIS-Teen)-2018,-Texas/. Accessed 10 Dec. 2019.
[5]"Historical Human Papillomavirus (HPV) Immunisation Coverage Rates." *Australian Government Department of Health*, Australian Government Department of Health, 4 Dec. 2019. *www.health.gov.au*, https://www.health.gov.au/resources/publications/historical-human-papillomavirus-hpv-immunisation-coverage-rates.

Texas: Feasibility of School-Based Vaccination

Although Australia and Texas differ greatly in terms of healthcare systems, staffing, and funding, school-based vaccination has been able to increase HPV vaccination rates in Texas as well as in Australia. Recently, a study was carried out that studied the effects of community-based HPV vaccination and school-based clinics on HPV vaccination rates in the Rio Grande City Consolidated School District (RGCISD) (Kaul et al. 1). Two schools received community-based education only (comparison school), while a third school had vaccination events in addition to education (intervention school). Pre-intervention, the intervention school had lower rates of vaccination initiation and completion than the comparison school (Kaul et al. 1). After

the interventions, all the schools improved their initiation and completion rates; however, the school that hosted both vaccination events and community-based education saw greater improvements (see table 6). Students attending the intervention school were over 3.6-times more likely to start and complete HPV vaccinations than students attending the comparison schools (Kaul et al. 5).

Table 6 School-based Vaccination and Community-Based Education Effects on HPV Vaccination in RGCISD (Kaul et al. 5)

School Type	HPV Vaccine Initiation	HPV Vaccine Completion
Pre-Intervention	20.0%	8.70%
Post-Intervention (vaccination events and community-based education)	53.67%	23.36%
Comparison School	28.97%	14.56%
Comparison School (community-based education only)	41.56%	20%

This aforementioned intervention improved vaccination rates in three Rio Grande Valley City schools; however, these rates have still not reached the Healthy People 2020 goal of 80% HPV vaccination, and they are lower than Australia's rates through school-based vaccination programs. Additionally, the Rio Grande Valley is just one area in Texas - further research must be conducted in order to assess if this project could be expanded to the rest of Texas.

Implications

Australia has managed to run a successful and voluntary school-based vaccination program that has resulted in high vaccination rates ("Historical Human Papillomavirus (HPV)

Immunisation Coverage Rates"). School-based vaccination programs have the potential to increase vaccine access, especially among students who face barriers to healthcare access (Kaul et al. 6). If school-based vaccination in Texas was implemented on a large scale and achieved similar rates to Australia, rates of HPV-associated cancers and genital warts would decrease, leading to quality-of-life increases for Texans. In the next chapter, I will detail the current state of HPV vaccination in Texas to emphasize the need for school-based HPV vaccination programs.

Chapter 2: HPV Vaccination in Texas

In this chapter, I will discuss specific elements of HPV vaccination that relate to implementing school-based HPV vaccination programs in Texas. I will begin this chapter with background information on HPV vaccination in Texas: vaccination rates, vaccine tracking, vaccine consent, political barriers, vaccine affordability, and access to healthcare. Then, I will apply the Health Behavior Model (HMB) to identify barriers to HPV vaccination and school-based vaccination specifically.

HPV Vaccination Rates in Texas

According to the National Immunization Survey, Texas lags behind national averages for HPV immunization coverage ("National Immunization Survey-Teen 2018, Texas"). In 2018, national initiation rates for females aged 13-17 was 69.9% and 66.3% for males. In contrast, Texas had HPV initiation rates of 64.6% for females and 55.5% for males in 2018 ("National Immunization Survey-Teen 2018, Texas"). Vaccine completion rates are even lower, with only 53.7% of females and 48.7% males aged 13-17 up-to-date on HPV vaccination (completed sequence) as of 2018 ("National Immunization Survey-Teen 2018, Texas"). Notably, all of these values fall below the Healthy People 2020 Goal of 80% completion rates of the two-dose HPV vaccination sequence ("2020 Topics & Objectives: Immunization and Infectious Diseases")

ImmTrac2: Texas' Vaccine Database

Texas has a centralized, confidential, and free opt-in immunization registry called ImmTrac2 ("ImmTrac General Public and First Responders"). The vast majority of parents decide to opt-in to the system at their child's birth (J. A. Boom, Sahni, et al., "Immunization

Information System Opt-In Consent" E19). Healthcare providers and payers, such as insurance companies, are required to report all vaccines given to minors to ImmTrac2 ("History of ImmTrac2"). In 2011, the system shifted from a children's-only vaccine registry to a lifelong registry ("History of ImmTrac2"). ImmTrac can be accessed by healthcare providers, child-care centers, schools, and other healthcare providers ("Requesting Immunization Records for a Child or Adult"). However, ImmTrac2 cannot be accessed by parents or guardians ("Requesting Immunization Records for a Child or Adult"). Rather, parents and guardians looking to view their child's vaccinations are told by the Texas Department of State Health Services to contact their child's doctor or school ("Requesting Immunization Records for a Child or Adult").

Additionally, ImmTrac2 vaccine records may contain errors. A survey conducted by Texas-based The Immunization Partnership in 2018 reported that 54% of vaccine stakeholders found the ImmTrac2 records to be incomplete ("Report on the State of the State December 2018" 51). This could be due to issues relating to electronic health records (EHRs) synching with Immtrac2. Further, while there have been incentives to switch to EHRs since 2009, some clinics may still use paper health records (Schmit et al. 585). In these cases, all of the vaccines these clinics administer must be manually entered into ImmTrac2. In the same study, survey respondents indicated that there are delays between uploading immunizations and them appearing in Immtrac2 ("Report on the State of the State December 2018" 48).

Immunization data must be manually entered separately into both ImmTrac2 and EHRs, unless there is a data exchange between the two systems ("Electronic Data Exchange - Meaningful Use"). This data exchange must be set up by either the EHR system the organization uses or the organization itself ("Electronic Data Exchange - Meaningful Use"). Further, even when the EHRs sync with Immtrac2, it is a one-way system. While some EMRs can

automatically send vaccination records to Immtrac2, vaccine records taken from Immtrac2 must be manually entered in EHRs ("Report on the State of the State December 2018" 51). Much like in the case of paper health records, this manual entry process increases the likelihood of human error.

Another problem with vaccine tracking is the lack of a nationwide system. Many states have their own vaccine-tracking system, and some even have multiple tracking systems within a single state ("Contacts for IIS Immunization Records"). Texas has only recently implemented a statewide system; some cities like San Antonio had their own system until as recently as 2017, when the enhanced ImmTrac2 debuted ("Immtrac2").

This can cause problems when people move across state lines. For example, during Hurricane Katrina, over 200,000 refugees fled to Houston from the New Orleans Area (J. A. Boom, Dragsbaek, et al. 1214). Many did not bring their medical records, resulting in an effort to track them down. The Houston-Harris County Immunization Registry (HHCIR) worked with the Louisiana Immunization Network for Kids Statewide (LINKS) to connect the two systems (J. A. Boom, Dragsbaek, et al. 1214). This resulted in the recovery of nearly 19,000 medical records, saving an estimated $3.04 million in revaccination costs (J. A. Boom, Dragsbaek, et al. 1215). In other cases, children's' vaccination records were not in the LINKS system. Workers tried to track down vaccination records by contacting medical homes and schools. In many cases the vaccination records were unable to be recovered, resulting in revaccination, which is costly and a waste of vaccination supplies (J. A. Boom, Dragsbaek, et al. 1216).

Consent to Vaccination in Texas

Texas requires consent from a parent, guardian, or conservator for vaccination ("Consent For Treatment of Minors"). However, in cases where one of them "is not available," adult siblings, grandparents, adult aunts or uncles, stepparents, educational institutions with written consent, another adult caring for the minor with written consent, a court with jurisdiction during a pending custody suit, and a primary caretaker with written consent from a parent may consent to vaccinations ("Consent For Treatment of Minors"). The phrase "is not available" is not legally defined and replaced the phrase "cannot be located" ("Consent For Treatment of Minors"). This prior phrase was better defined to apply to parents with unknown location; there has been a "reasonable effort" to locate the parent; or the parent has been contacted, will not testify, and does not deny consent for vaccination ("Consent For Treatment of Minors").

Unique Political Barriers in Texas

Texas has unique political barriers in the way of meeting the Healthy People 2020 goal of 80% HPV vaccination coverage. In 2007, then-Governor Rick Perry announced an executive order mandating the HPV vaccine for young girls in Texas (Bustillos 9). This unexpected announcement - and the fact that a former Perry staff member was now a lobbyist for the HPV manufacturer - led to accusations of corruption (Bustillos 9). Dr. Dan Bustillos served on the Cervical Cancer Strategic Planning Initiative's (CCSPI) Policy Work Group, which was invited to send policy recommendations to the Governor's office.

In late 2005, Dr. Dan Bustillos participated in a task force on cervical cancer while the HPV vaccine was still in development. Because research on safety and efficacy was still ongoing at the time, they needed to work directly with Merck, the pharmaceutical company developing

the vaccine, to access the unpublished data. However, he soon became uncomfortable with Merck's level of involvement with creating the proposal (Bustillos 7).

Through his work on the task force, he found that Merck was the primary driving force behind the push for Texas to enact assertive vaccination policies that they would benefit from financially, even as the task force tried to limit their involvement to what was necessary (Bustillos 7). The task force did not recommend mandatory vaccination; they felt that increasing access to the vaccine was more likely to pass in Texas and fit better with the political and cultural climate (Bustillos 8). Shockingly, then-governor Rick Perry announced measures to mandate the vaccine for young girls in Texas - far more severe than the task force's recommendations to increase access - just days after receiving the task force's extensive memo (Bustillos 8). This decision was in sharp contrast to what was expected in light of Perry's conservative views (Bustillos 8). Additionally, at the time of Perry's executive order, several of Perry's political allies, conservative Christian groups and the Republican party were speaking out against the vaccine, claiming that it was unsafe and would result in promiscuity among young girls (a claim since disproven in many studies such as Madhivanan et al.) (Bustillos 8).

Perry's mandate did not pass in Texas, and later it was discovered that Perry's former chief of staff joined Merck as a lobbyist prior to the order and also formed a large pro-Perry Super-PAC (Bustillos 9). Throughout the lobbying process, Merck was also contributing to Perry's campaign both directly and indirectly (Bustillos 9). It is impossible to know the true extent of this political failure on HPV vaccination rates in Texas. However, it is possible that this event is one of the factors that causes Texas to lag behind in HPV vaccination rates.

Texas: Healthcare Access and Vaccine Affordability

Nearly 5 million out of the 29 million total Texans are uninsured and may face financial barriers to healthcare services ("Health Insurance Coverage in the United States"). Additionally, the people that live in one of Texas' 172 rural counties may face additional barriers in accessing healthcare, such as lack of affordable transportation or low numbers of healthcare providers (*Definitions of County Designations*). HPV vaccination is especially important in South Texas because the incidence of cervical cancer is higher than in the state as a whole: 10.5 per 100,000 people compared to 9.3 per 100,000 people (Ramirez et al. 36). In the Rio Grande Valley, both uninsurance rates and cervical cancer mortality are higher than the state average. The region has an uninsurance rate of 33.5% and cervical cancer mortality is 30% higher in the Rio Grande Valley when compared to non-border counties in Texas (K. Boom et al. 199).

There are several programs that provide vaccines to children for either free or at a reduced charge. The main program in Texas is called Texas Vaccines for Children, a state-specific offshoot of the federal Vaccines for Children program. The vaccines themselves are free to providers; however, providers are allowed to charge a small administration fee (*Information for Providers - Texas Vaccines for Children*). Many children under the age of 18 in Texas qualify for this program, including uninsured or underinsured children, CHIP recipients (low-cost health insurance children who are low-income but who do not qualify for Medicaid), children on Medicaid, and children who are Native American or Native Alaskan (*Information for Providers - Texas Vaccines for Children*).

Parent-Level Barriers to HPV Vaccination

A 2014 meta-analysis published in JAMA Pediatrics analyzed 55 papers about barriers to HPV vaccination and classified them according to the population studied (Holman et al. 76).

Holman found that healthcare providers are likely to cite both parent attitudes and financial concerns as the chief barriers to vaccination (Holman et al. 76). In the same study, parents cited a multitude of barriers, mostly related to wanting more information about the vaccine before vaccinating their children (Holman et al. 76). Some parents wanted to know if the vaccine would lead to more risky sexual behavior (1-18%), while others did not believe their child was at risk for infection (Holman et al. 78). This was especially present among parents of young boys (Holman et al. 77). Other parental barriers included the cost of vaccination and irregular access to healthcare (Holman et al. 76). The most important factor for parents in many of the studies was a provider recommendation for the vaccine (Holman et al. 76).

Although provider recommendation is an important factor influencing a parent's decision to vaccinate, there are disparities in who receives them (Gerend et al. 106). A study conducted in Florida in 2015 surveyed 223 people aged 18-26 and found that people were more than 35 times more likely to receive a dose of the HPV vaccine if they were given a provider recommendation (Gerend et al. 106). Further, the study found that age, race, insurance status, and gender independently predicted provider recommendations, with white, insured, female participants the most likely group to have received a recommendation (Gerend et al. 106). This study emphasizes that provider recommendations are not given equally to all demographic groups. Disparities in provider recommendations lead to disparities in vaccination rates, which could lead to increases in cancer incidence in groups that already have barriers to healthcare. In the United States, cervical cancer incidence varies among demographic groups and regions.

Parental Intention and Vaccine Uptake

A 2016 paper conducted qualitative interviews with parents at a school-based health center and sought to define the "vaccine intention-behavior gap:" the previously observed data that intent to vaccinate is often higher than actual vaccine initiation rates (Auslander et al. S27). They found that parents that intended to vaccinate and followed through on their intention vaccinated their children immediately after they decided to do so (Auslander et al. S27). This indicates that vaccination opportunities close in time to the decision to vaccinate have the potential to improve vaccination rates.

Additionally, a meta-analysis of 79 studies that surveyed parents on HPV vaccination found that there were eight main factors positively associated with HPV vaccine uptake: (Newman et al. 5)

1. HPV vaccine recommendations and trust of healthcare provider
2. Mothers are more likely to vaccinate than situations where both parents decide
3. Constructs of the Health Belief Model (HBM): intentions to vaccinate, attitudes about the vaccine, beliefs about safety concerns/perceived benefits about the HPV vaccine and vaccines more generally
4. Access/use of preventative healthcare services like yearly checkups
5. Affordability: insurance coverage for HPV vaccination
6. Parent HPV history
7. Parent education about the risks of HPV, cervical cancer
8. Urban as opposed to rural location, age of child

Many of the factors that contribute to the vaccine intention-behavior gap can be thought of through the lens of the Health Belief Model.

The Health Belief Model and HPV Vaccination

The Health Belief Model (HBM) is a framework that was created in the 1950s by Hochbaum, Kegels, and Rosentock at the U.S. Public Health Service (Glanz et al. 76). It is used to illustrate the factors that play into someone partaking in certain activities relating to health. In particular, it takes into account the perception of threat severity and behavioral characteristics (Conner and Norman 49). The HBM has been used in several studies to predict health behaviors including contraception use, exercise habits, and vaccination (see figure 1)(Conner and Norman 49).

Figure 1 Components of the Health Belief Model (Glanz et al. 79)

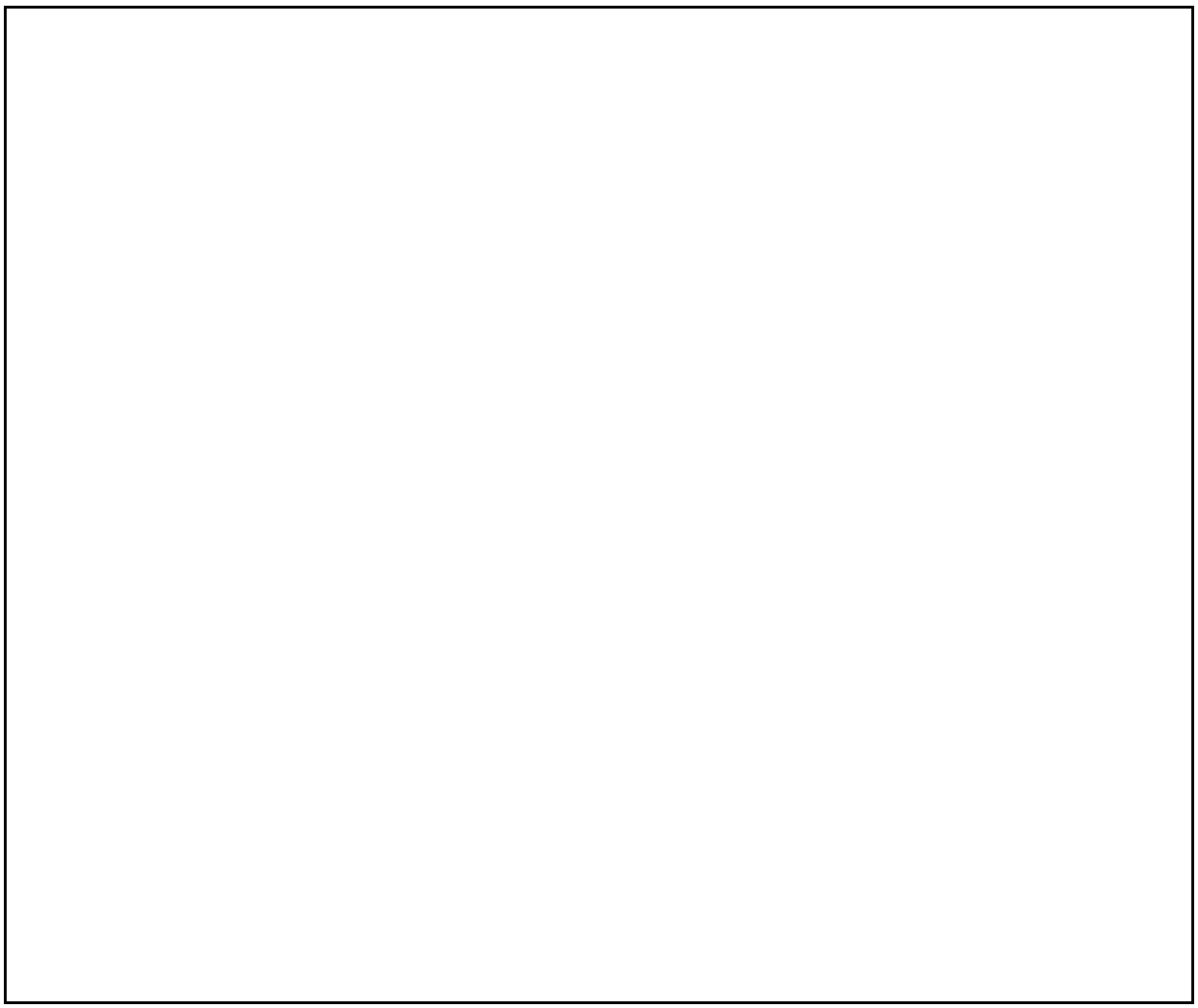
I will apply the HBM to HPV vaccination to assess barriers to vaccination and to craft targeted approaches to increase vaccination rates. For example, a parent not believing that their young child is at risk for contracting HPV because they are not sexually active could fall under "perceived susceptibility" in the model. A targeted approach to overcome this error in perception

could be an education intervention explaining the reason why the vaccine is recommended for young children.

When applied to the HPV vaccine, the HBM explains parents' perceived barriers or benefits to HPV vaccination on an individual level. Fernández et al. uses some elements of the HBM and expands it, including environmental factors, including interpersonal, organizational, and community/societal elements to create a model for HPV vaccination decision-making (see figure 2). Thus, it is an important tool in light of the purpose of this thesis as it can aid in understanding how school-based vaccination can impact intent to vaccinate.

Parent consent is required for minors to be vaccinated in the vast majority of circumstances. Therefore, factors influencing parents' decisions to vaccinate their children are very important in studying vaccination. A meta-analysis conducted in 2010 by Fernández et al found the following factors influence parental decisions regarding vaccination and applied them to the HBM framework: perceived barriers, age-appropriateness concerns, and concerns about the HPV vaccine leading to risky sexual behavior (see figure 2) (Fernández et al. 5). Knowledge about the vaccine, perceived susceptibility to HPV, and perceived severity of HPV and HPV-associated cancers also influence parental decision-making (Fernández et al. 5). Intention and willingness to vaccinate, along with environmental factors that encourage and enable vaccination, can translate to HPV vaccination, which will ultimately reduce the burden of HPV-associated diseases (Fernández et al. 11). These findings were used to create figure 2, which serves as a proposed model for the factors that influence parental intent to vaccinate (Fernández et al. 9).

Figure 2: Applying the Health Belief Model to HPV Vaccination (Fernández et al. 19)



School-based Vaccination and the Health Belief Model

School-based vaccination is able to work within the parameters of the health belief model to educate parents and provide them with an opportunity to vaccinate, therefore equipping parents to follow through on their intentions to vaccinate. (see figure 2). School-based vaccination programs differ, but for the purposes of this paper they will involve the following general format: consent forms are sent home based on vaccination records, and healthcare professionals (often third-party contractors) come to deliver vaccines to children at schools. They

can offer required vaccines, recommended vaccines like HPV, or seasonal vaccines such as the flu.

When I refer to school-based vaccination programs, I am excluding school-based health centers. School-based health centers offer a variety of services to students and surrounding communities and may be located near or on a school campus. In addition to vaccinations, they may offer services including routine exams and physicals, dental exams, mental health services, and acute care ("School-Based Health Centers"). While school-based health centers do often offer vaccinations, I will be focused on school-based vaccination clinics for the purposes of my thesis.

School-based vaccination programs have the ability to address some of the barriers that stand in the way of increased HPV vaccination rates. Programs operate in conjunction with school nurses, and a form that gets sent home includes all of the available vaccines (Rodriguez). By sending home a list of vaccines with consent forms, the school nurse is effectively recommending the vaccine. This addresses the environmental interpersonal factor of "clinician recommendation" (see figure 2).

Further, if school-based vaccination programs are coupled with educational interventions run by experts, it will address parent concerns and education lapses. School-based vaccination clinic information interventions can be tailored to address the educational factors and beliefs that influence parents in vaccinating their children. This includes vaccine safety and efficacy, HPV-related disease susceptibility, and the benefits of the vaccine (figure 2).

School-based vaccinations are also convenient; they do not rely on regular access to preventative care. Rather, children can receive immunizations while they are at school. This falls under the community/social environmental factors section of the Fernández et al HBM model

(see figure 2). School-based vaccination increases the availability of the HPV vaccine, as parents do not have to make appointments or travel arrangements beyond their children attending school. This is especially important in multi-dose vaccines such as HPV, which involve two or three vaccinations several months apart (Meites et al. 700).

School-Based Vaccination and Appointment Scheduling

A study from the University of Rochester attempted to determine how many additional appointments would be required in order for adolescents to complete a three-dose sequence of the HPV vaccine (Rand et al. 461). (Note: since the study has been conducted, a two-dose quadrivalent HPV vaccine is now in use). Many adolescents do not see their primary care physician at least once a year, with various studies quoting statistics that vary from 34% to 82% of adolescents with at least one visit (Rand et al. 462). Consequently, the study found that 23% of female patients and 37% of male patients would need three additional appointments in order to complete the sequence, with the majority of children needing at least two additional appointments (Rand et al. 461).

Further, the same study found that children that are poor, black, Hispanic, or uninsured are more likely to need more appointments (Rand et al. 462). The HPV vaccine requires two doses given at least six months apart for children under the age of 15, and three doses for patients over the age of 15. Therefore, the vaccine sequence cannot be completed in a single visit, and additional visits must be scheduled in order to complete it. The need for multiple visits within a year can also cause strain on primary care doctors, who must schedule multiple timely appointments for additional vaccination needs (Rand et al. 462).

Parental Acceptance of School-Based HPV Vaccination

While school-based vaccination seems to tackle some of the challenges present in HPV vaccination, some survey results indicate that the majority of parents may not feel comfortable with it. However, while parents may not appear eager to utilize school-based vaccination based off of survey results, their actual uptake may be higher in practice.

One study conducted in Houston Independent School District where parents were instructed to check all statements that apply found that 41% of parents surveyed cited school-based vaccination during school hours as a preferred vaccination location (Middleman and Tung, "At What Sites Are Parents Willing to Have Their 11 through 14-Year-Old Adolescents Immunized?" 2676). In comparison, 65% of parents selected a medical home as a preferred location (Middleman and Tung, "At What Sites Are Parents Willing to Have Their 11 through 14-Year-Old Adolescents Immunized?" 2676). The most common reason parents cited for not wanting school-based vaccination was that they desired to be with their child when they got vaccinated (67% of parents that did not indicate a school-based program would be preferred)(Middleman and Tung, "At What Sites Are Parents Willing to Have Their 11 through 14-Year-Old Adolescents Immunized?" 2676).

A later follow-up study found that some parents that did not believe schools to be a "preferred location" for vaccinations still vaccinated their children through school-based programs (Middleman and Tung, "School-Located Immunization Programs" 2516). The study was carried out in five Houston middle schools through surveys which assessed parental preferences regarding vaccination (Middleman and Tung, "School-Located Immunization Programs" 2516). The schools were in low-income, urban areas, and primarily served Hispanic students. Of the 475 parents that responded to the survey, 61% consented for their children to

receive at least one vaccine at the school-based clinic (Middleman and Tung, "School-Located Immunization Programs" 2516). Of the 61% that received vaccinations, 42% of parents had previously responded that schools were not a preferred vaccination location (Middleman and Tung, "School-Located Immunization Programs" 2516). This finding indicates that surveys measuring parental preference may not accurately predict behavior. Further, parents may be open to school-based vaccination in practice when they object to it in theory.

While neither of these studies were for the HPV vaccine, they indicate that more parents may consent to school-based vaccination for their children than is indicated in surveys. Additionally, the majority of "true refusers:" parents that indicated on surveys that they did not prefer school-based vaccination and also did not use the school-based program, indicated on the survey that they preferred to be present when their child was vaccinated (Middleman and Tung, "School-Located Immunization Programs" 2516). This implies that school-based vaccination clinic uptake may be higher if parents are given this option.

Conclusion

Texas has lower HPV vaccination rates and higher incidence of cervical cancer than the nation as a whole ("National Immunization Survey-Teen 2018, Texas"). School-based vaccination has the ability to address key points on the HBM as it relates to HPV vaccination as it can include educational interventions and provide additional opportunities for vaccination. In the next chapter, I will discuss Australia's successful school-based vaccination program that includes HPV. While Australia and Texas differ in healthcare systems, vaccine tracking, and political barriers to HPV vaccination, I will identify elements of Australia's program that could be translated to school-based HPV vaccination interventions in Texas.

Chapter 3: School-Based Vaccination in Australia

Australia has a largely successful school-based vaccination program that provides free vaccines, including the HPV vaccine. In this chapter, I will examine Australia's government structure, healthcare system, immunization tracking, and its school-based vaccination program, with a focus on how it has overcome barriers relating to HPV vaccination. I will apply these lessons-learned to Texas programs in future chapters.

Government Structure

Australia is split into states and territories (*State and Territory Government*). The six states (Tasmania, Victoria, New South Wales, Queensland, Western Australia, and South Australia) have their own state governments and pass legislation (*State and Territory Government*). If there is a conflict between state and federal law, federal law prevails. Additionally, there are three internal territories and seven external territories, three of which have permanent residents (note: external territories not shown in figure 3) (*State and Territory Government*). The territories have various levels of self-governance, but their powers are from the Australian Parliament, rather than the Constitution.

Australia has a very urban population, with nearly 90% of its inhabitants living in cities ("Australian Historical Population Statistics, 2016"). At the same time, the country is very sparsely populated. As of 2016, the population density was 3.1 people per square kilometer, with most people living along the coasts ("Regional Population Growth, Australia 2016").

Figure 3: Map of Australia, taken from (Jones)

Cervical Cancer Prevalence

Australia has been able to achieve some of the lowest rates of cervical cancer incidence and mortality through a combination of increased cervical cancer screening and school-based HPV vaccination (Hall et al. e19). A modeling study from the Lancet predicted that there will be fewer than six new cases of cervical cancer per 100,000 Australian women in 2020, compared to 10.5 new cases per 100,000 women in Texas (Hall et al. e19)(Ramirez et al. 36). Hall et al. also predicted that this rate would decrease to less than four cases per 100,000 by 2028 and one case per 100,000 by 2066 (Hall et al. e19). Australia is on its way to essentially eradicate cervical cancer. Australia's school-based HPV vaccination program is a major factor in these decreases.

Healthcare System

The school-based vaccination program and cervical cancer screening campaign is funded by Australia's single-payer healthcare system, Medicare. Medicare is funded by general tax revenue, as well as by the Medicare levy, which is currently set at 2% of taxable income ("Medicare Levy"). It allows for free or subsidized outpatient healthcare services, free treatment at public hospitals, and subsidies on services in private hospitals ("What Is Medicare?"). Generally, Medicare covers the entire cost of general practitioner appointments, 85% of specialist appointments, and 75% of inpatient services ("What Is Medicare?"). In addition to Medicare, over half of Australians choose to purchase supplementary private insurance to help pay for private hospitals or reduce wait times for elective procedures (Shamsullah 25). Mid-level earners can qualify for government subsidies for private insurance premiums, and high-level earners can face fines for not purchasing private, supplementary insurance plans (Shamsullah 25). In addition, high-earning Australians who do not purchase private plans by the time they turn 30 may face higher insurance premiums if they buy private plans later as a consequence (Shamsullah 25).

All Australian and New Zealand citizens, as well as permanent residents, are eligible to enroll for Medicare coverage (*How to Enrol and Get Started in Medicare - Enrolling in Medicare - Services Australia*). All vaccines that are a part of the National Immunisation Program Schedule are provided to Medicare recipients free of charge. This includes childhood vaccines, vaccines for the elderly, and certain vaccines for people at higher risk such as the flu vaccine for pregnant women ("National Immunisation Program Schedule").

Vaccination Incentives Versus Requirements

Australia does not require vaccines for entry into public schools. However, if there is a disease outbreak, children that are not vaccinated may be required to stay home (Walkinshaw E1167). Additionally, parents are offered financial incentives for keeping their children up-to-date on early childhood vaccinations. If children are up-to-date on vaccination requirements, parents receive $129, both between 18 and 24 months of age as well as between ages four and five (Walkinshaw E1167).

In September 2017, Australia passed legislation that bars unvaccinated children from daycares and preschools. The law was nicknamed "no jab, no play," and was protested by anti-vaccine groups (Baidawi). There are only medical exemptions, no philosophical or religious exemptions, and daycares that admit unvaccinated children are eligible to receive fines up to 30,000 Australian dollars (Baidawi). Medical exemptions in Australia can be granted as a result of anaphylaxis connected to a vaccine, significant immunocompromisation, or natural immunity ("Immunisation Medical Exemptions"). Additionally, since 2016 parents were denied certain welfare rebates and other government benefits if they refused to vaccinate their children (Baidawi). These losses from not vaccinating could total up to 15,000 Australian dollars in some cases (Baidawi).

School-Based HPV Vaccine Program Origins

School-based vaccinations have a long history in Australia. The first vaccines administered in a school setting were for the diphtheria-tetanus toxoid (dT) vaccine from 1932 to 1936 (Ward et al. E168). Additional programs were put into place from the late 1940s to the mid-1980s for the bacille Calmette-Guerin (BCG) (Ward et al. E168). Additionally, some territories used schools as a Polio vaccination site in the 1950s and 1960s. These Polio programs

were in addition to mass-vaccination programs in communities (Ward et al. E168). As of 2007, all states and territories had a major school-based vaccination program (Ward et al. E169).

Queensland was the last state to have widespread school-based vaccinations. Prior to the state-level programs, people were vaccinated at general practitioners' offices and some local school-based programs ("Evaluation of the School Based Vaccination (2007-2009) Program Stakeholders' Report" 4). Between 2007-2009, the first two years of the program, overall vaccination coverage among adolescents increased from 30% to 60% ("Evaluation of the School Based Vaccination (2007-2009) Program Stakeholders' Report" 3).

School-Based HPV Vaccine Program Structure

In November 2006, the Australian government announced that they were adding Gardasil to the National Immunisation Program for 2007, meaning that the HPV vaccine would be offered for free to Australian females aged 12 to 26 years old ("History of Immunisation in Australia"). Girls aged 12 and 13 received the vaccines in a school setting, with an additional two-year catch-up program in schools for girls aged 13 to 18 ("History of Immunisation in Australia"). Women aged 18 to 26 could receive the vaccine for free from their general practitioner ("History of Immunisation in Australia"). Australia started vaccinating boys aged 12-13 years old for HPV in February 2013 and offered a two-year catch-up program for boys 14 to 15 years old as well (Ward et al. E172). Now that the HPV vaccine is a part of the National Immunisation Program, Australian students are routinely vaccinated for HPV in schools during either school year 7 or 8, depending on the state.

Procedures within the school-based vaccination clinics can differ between states. Generally, consent forms along with educational materials are sent with children to bring home

to their parents (Garland et al. S30). After the consent forms are signed, they are returned to the school (Garland et al. S30). On vaccination day, children with signed consent forms receive the vaccine. The vaccines are delivered during school hours by trained vaccination providers. There is educational material for the vaccine that is aimed at parents, and there are no requirements for schools to educate the children receiving the vaccine (Garland et al. S30). Additionally, the schools function as vaccination sites, but do not run the vaccination clinics, rather it is the responsibility of the states' health departments (Garland et al. S30). Therefore, the schools generally do not run any educational programming. Funding for the vaccinations occurs on a country and state/territory level. The states and territories are responsible for funding vaccine delivery, while the Commonwealth supplies the vaccine to the school-based vaccination clinic for free (Dey et al. 18).

Evaluating Australia's School-Based HPV Vaccination Programs

To determine the success of each vaccination program within the National Immunisation Program, the Australian Department of Health partnered with the National Centre for Immunisation Research and Surveillance (NCIRS), which is affiliated with the University of Sydney ("Program Evaluation"). The NCIRS uses "process evaluation" and "impact evaluation," to assess programs ("Program Evaluation"). The impact evaluation includes "vaccination coverage," "seroepidemiology," and "vaccine safety" in addition to reduction in disease burden ("Program Evaluation"). The NCIRS' evaluation of the National HPV Vaccination Program was completed in 2014. The evaluation omitted data from boys because at the time of the report, boys had not yet completed three doses of the vaccine (Dey et al. 14).

Process Evaluation. Process evaluation of the school-based clinics themselves was assessed through interviews with vaccination stakeholders (Dey et al. 15). The interviews revealed that stakeholders saw the HPV vaccination program as a success. However, they identified two issues with the initial program for female students:

1. They found it difficult to schedule three doses for large numbers of students during the school year.
2. "Late availability of information resources," for parents, particularly in regard to the safety of the vaccine, the prevalence of adverse events, and the concern that vaccination against HPV may encourage sexual behavior in adolescents (Dey et al. 17).

Another area for improvement in the program was communication with outside providers. Vaccination data from school-based vaccination days needed to be shared with vaccine providers in the community so that they can deliver missed doses outside of the school setting (Dey et al. 18). Even though there were challenges, stakeholders still felt that school-based settings were ideal for vaccination because it is an effective strategy for improving vaccination rates and reaching youth (Dey et al. 18).

Further, they credited the success of the male program to the acceptance of the female program. Providers remarked that acceptance of the male program was high and attributed it to the female program through the National Immunisation Program, greater parental knowledge of HPV, and fewer concerns about a possible link between vaccination and risky sexual activity (Dey et al. 17). When implementing the male program, they were able to improve upon the existing female program. They made improvements such as bettering adverse event tracking and providing parents with more information about the vaccine (Dey et al. 18).

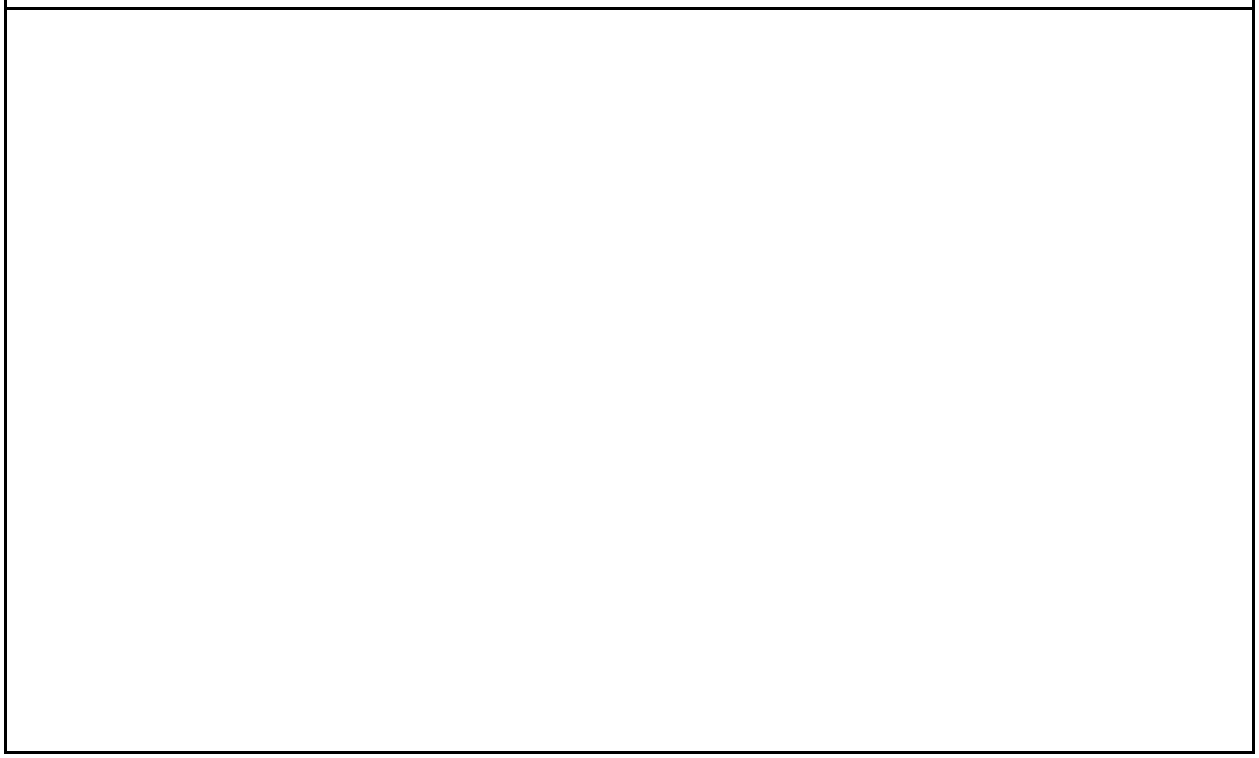
Impact Evaluation. Impact evaluation involves assessing changes in the burden of disease, including vaccine coverage rates, safety, and outcomes. Vaccination rates were evaluated by socioeconomic status and population density (Dey et al. 15). Vaccine safety was determined by tracking adverse events following immunisation that were recorded in the Adverse Drug Reaction System (ADRS) database (Dey et al. 16). Disease impact was evaluated through rates of "high grade cervical abnormalities" and hospital visits for genital warts (Dey et al. 16).

The school-based HPV vaccine program was able to achieve very high vaccination rates in a short amount of time. As of 2007, the first year that the vaccine was funded through the National Immunisation Program, vaccination rates for adolescents 12-17 years old within school-based programs was 83% for dose 1, 78% for dose 2, and 70% for dose 3 (Dey et al. 18). These rates differed across states and territories, which may indicate that there could have been small differences in program implementation that resulted in higher or lower vaccination rates (Dey et al. 19). Additionally, there were no major differences in vaccination rates between high and low socioeconomic statuses or rural and urban areas. The variance between the areas of highest and lowest SES was largest for 3-dose coverage at 5%, and there was less than 1% difference for vaccine initiation (Dey et al. 19). Additionally, vaccination rates between rural and urban areas tend to be relatively equal (Dey et al. 19).

More recently, HPV vaccination rates still vary between states and territories, but they are generally high. According to the National HPV Vaccination Program Register, girls turning 15 had an average HPV vaccination rate of 88.9% for dose 1, 86.0% for dose 2, and 80.2% for dose 3 in 2017 (the most recent year for which there is data available) ("Historical Human Papillomavirus (HPV) Immunisation Coverage Rates"). For males turning 15 in the same year the rates were 85.0% for dose 1, 81.9% for dose 2, and 75.9% for dose 3 ("Historical Human

Papillomavirus (HPV) Immunisation Coverage Rates"). A comparison of HPV vaccination rates in Texas and Australia for 2017 is shown in figure 7.

Figure 7: 2017 Vaccination Rates, Texas and Australia
AUS data: ("Historical Human Papillomavirus (HPV) Immunisation Coverage Rates")
TX data: ("NIS Data Tables for 2015 to Present")

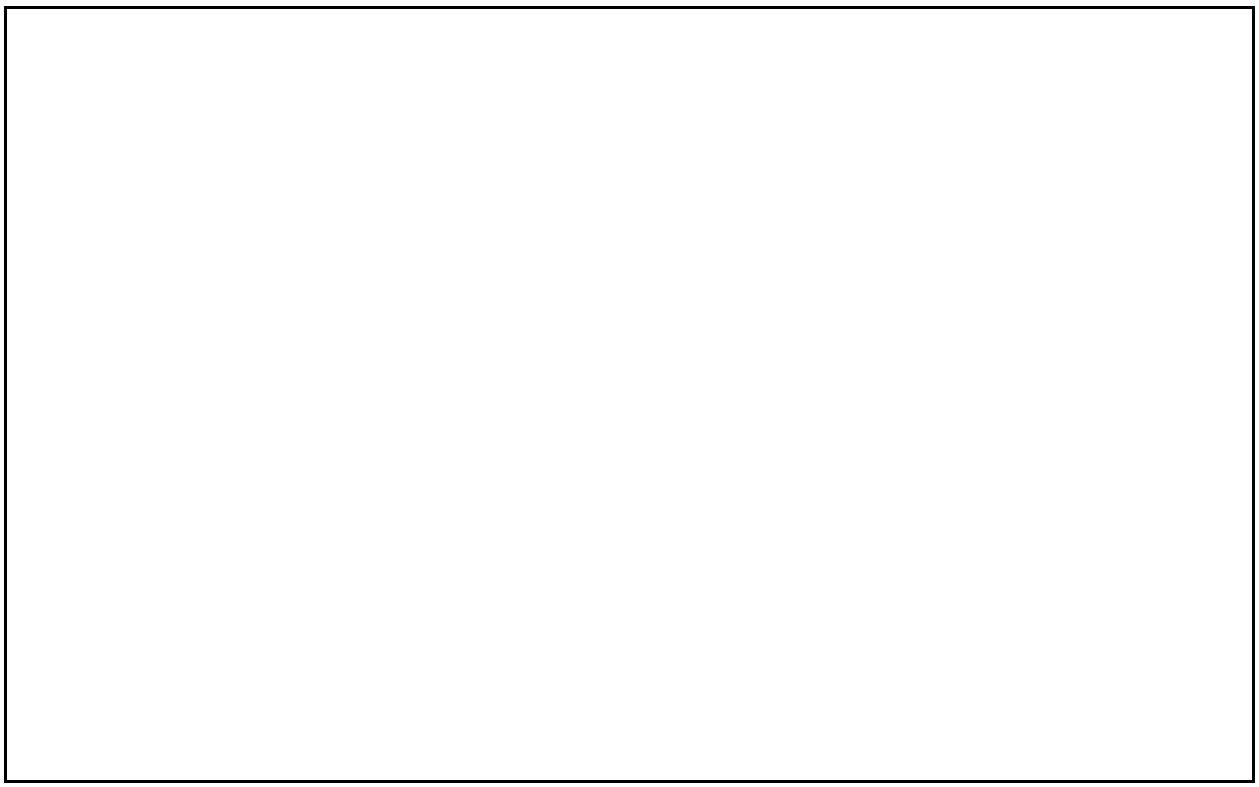


The adverse events records database contains 4356 reports for the Gardasil vaccine between 2007 and 2019 ("Database of Adverse Event Notifications"). The number of adverse events reported appears to be greatest when new vaccine programs were introduced (see figure 4). The data below reflects that the launch of school-based HPV vaccines for girls in 2007 and for boys in 2013 resulted in the highest number of adverse events reported. Additionally, the adverse event database increased its surveillance in 2013, leading to higher reporting (Dey et al.

19). The vast majority of adverse events reported were mild such as headache, dizziness, and nausea (Dey et al. 19).

Figure 4: Reported Gardasil Adverse Events 2007-2019, Australia ("Database of Adverse Event Notifications")

Figure 5: Reported Gardasil Adverse Events 2007-2019, Texas ("The Vaccine Adverse Event Reporting System (VAERS) Results Form")



The HPV vaccine also had a noticeable impact on cervical abnormalities and rates of genital warts. Rates of high-grade cervical abnormalities continue to decrease, resulting in a 45% reduction in 2011 compared to the 2004-2007 pre-vaccine period comparison (Dey et al. 20). Also, compared to 2006-2007, there was an 89.9% reduction in hospitalizations relating to genital warts in 2010-2011 for females aged 13-17 years old, and a 72.7% reduction for females aged 18-26 (Dey et al. 21). This indicates that widespread HPV vaccination is having the intended effect: it has resulted in lower rates of HPV-associated symptoms and will likely result in lower rates of HPV-associated cancers as vaccinated people age.

HPV vaccination was introduced in Australia after the widespread adoption of school-based vaccination, so it is difficult to assess how much of this success is due to school-based vaccination alone. However, the impact and process evaluations mentioned indicate that school-based vaccination has been successful in Australia. Surveyed stakeholders see the value of

school-based vaccination and believe it is a good way to reach adolescents. The increases in HPV vaccination rates verify that the program has been effective among students of different socioeconomic statuses in both rural and urban areas. Additionally, it has resulted in reductions in possible pre-cancerous cells in the cervix as well as genital warts, as expected.

Keys to Success in Australia

Much of Australia's successes with HPV vaccination are due to the deconstruction of barriers to vaccine receipt and completion. In particular, Australia's National Immunisation Program makes the HPV vaccine free for all qualifying children ("National Immunisation Program Schedule"). Additionally, all of the states and territories in Australia already have pre-existing school-based vaccine programs, in which the local health departments coordinate with schools to deliver vaccines ("Evaluation of the School Based Vaccination (2007-2009) Program Stakeholders' Report" 4). School-based vaccination also may be more normalized in Australia because of its history, which could lead to more parental trust of schools as a vaccination location. However, there are still some unique features that are a part of Australia's school-based vaccination program that can be implemented elsewhere. These techniques could help to create successful HPV vaccination programs even in countries without single-payer healthcare or existing school-based vaccination infrastructure.

First, vaccination data is uploaded to the Australian Immunisation Register, where it can be assessed by patients and healthcare providers. It includes vaccines that were given as a part of the National Immunisation Program, in schools, and privately (*Australian Immunisation Register - Services Australia*). Parents are able to log in to see what recommended vaccines their children are missing, which may encourage them to pursue vaccination. This also allows the Australian

government to send reminders to general practitioners and parents about vaccines that children may be missing. It also allows for the Australian government to track vaccination rates. For the HPV vaccine, the system is used to send out a notification through the system that children are overdue for their HPV vaccination at 14.5 years of age to parents (*Australian Immunisation Register - Services Australia*). Previously, there was a separate registry for HPV vaccination data: The National HPV Vaccination Program Register ("Using the Australian Immunisation Register"). However, now all vaccines are recorded in the Australian Immunisation Register ("Using the Australian Immunisation Register").

Second, the Australian Government Department of Health has released a series of videos on what to expect during school-based vaccination for many of the vaccines in the National Immunisation Program Schedule. The videos are aimed toward students and describe the process of getting vaccinated, how vaccines work, and the importance of the vaccine that is going to be delivered in school ("Vaccination Videos for High School Students"). Additionally, there are videos geared toward certain demographics, such as Aboriginal and Torres Strait Islander audiences ("Talk to Your Mob about HPV – Animation Video for Aboriginal and Torres Strait Islander Audiences"). These videos serve to comfort children and parents and could be used to help normalize school-based vaccination in areas where it is not commonplace.

Conclusion

Australia is on-track to essentially eradicate cervical cancer by 2066 (Hall et al. e19). This is partially due to its successful school-based HPV vaccination program, which is funded as a part of Australia's National Immunisation Program. Successful elements of Australia's school-based vaccination program include the ability to send notifications through the Australian

Immunisation Register and its targeted videos describing the school-based vaccination process. Some of the challenges that stakeholders mentioned in regards to school-based vaccination include scheduling difficulties (as the vaccine requires multiple doses) and parental concerns regarding the safety of the vaccine, the prevalence of adverse events, and the concern that vaccination against HPV may encourage sexual behavior in adolescents (Dey et al. 17). These barriers to vaccination were similar to those seen in Texas, yet Australia was still able to achieve high vaccination rates. In the next chapter, I will explore two Texas case studies: Dr. Cuccaro in Houston and Dr. Rodriguez in the Rio Grande Valley. Ultimately, I will determine if elements of Australia's successful school-based HPV vaccination program could be applied to existing and future projects in Texas.

Chapter 4: School-Based Vaccination in Texas

The Utility of School-Based Vaccination Programs

As previously stated in other chapters, the U.S., and especially Texas, lags behind in HPV vaccination rates. The vast majority of these vaccinations occur in clinic settings, where multiple appointments are required to get the doses needed for full HPV protection (Rand et al. 462). This is another barrier to HPV vaccination coverage, and its negative effect on vaccination rates could be lessened through implementing more school-based vaccination programs in Texas.

Offering the HPV vaccine through schools has the potential to lead to better vaccination outcomes because they eliminate the need for scheduling appointments in order to receive the vaccine. Additionally, school-based vaccination sites can be tailored to avoid barriers in place that make it difficult for some children to receive healthcare services. For example, scheduling conflicts, like the fact that many doctors' offices are only open during school hours, may become a barrier and can be mitigated through school-based vaccination (Middleman and Tung, "At What Sites Are Parents Willing to Have Their 11 through 14-Year-Old Adolescents Immunized?" 2676). School-based vaccination clinics can be operated during school hours or after school and may result in less missed class time if parents opt to vaccinate their children in schools as opposed to traveling to a clinic appointment (Rand et al. 462).

Methodology

There are few, ongoing projects aimed at increasing HPV rates through school-based vaccination programs in Texas. I will focus on two: Dr. Ana Rodriguez in the Rio Grande Valley, and Dr. Paula Cuccaro in Houston. Both are funded through the Cancer Prevention and Research Institute of Texas (CPRIT Grant IDs; Rodriguez: PP190023, PP160097; Cuccaro:

PP170046, PP200017). Both of these projects were selected because they fit the general structure of school-based vaccination described in previous chapters and are located in Texas.

I conducted two roughly 40-minute phone interviews with Dr. Rodriguez and Dr. Cuccaro and asked them about the barriers and successes they have found in their programs. The interviews were voluntary, and no compensation was provided. Both interviews were recorded so they could be transcribed later. I also took limited notes during the interviews. The interviews started with set questions but became conversational. I asked questions relating to the literature background of their research, their experience starting the project, program structure, changes over time, barriers to implementation, parent/administrator/clinic staff reception, and how HPV vaccination compares to other vaccines. These questions were designed to provide an overview of the programs and allow me to compare the barriers that different programs faced in order to find ways to best address them. I used my interview notes along with published studies and statistics from the researchers to inform this chapter. Additionally, I visited one of Dr. Rodriguez's school-based vaccination events in McAllen, Texas. After describing the structure of the programs and evaluating their successes and barriers, I will compare them to Australia's school-based HPV vaccination program in subsequent chapters.

Case Study 1: Dr. Ana Rodriguez, School-Based Vaccination in the Rio Grande Valley

Dr. Ana Rodriguez's project is in several counties in the Rio Grande Valley: Starr, Hidalgo, Willacy, and Cameron, as well as three counties in the Laredo area: Jimm Hogg, Webb, and Zapata (K. Boom et al. 199). These areas are mainly rural and have a total combined population of 1.5 million people as of 2018, with a poverty rate of 31.8% (K. Boom et al. 199). Additionally, the region has an uninsured rate of 33.5% and cervical cancer mortality is 30%

higher in the Rio Grande Valley when compared to non-border counties in Texas (K. Boom et al. 199). Further, people who live in the Rio Grande Valley are more likely to have low health literacy and to be medically underserved when compared to other areas in Texas (K. Boom et al. 199). Prior to recent projects in the region, there were very few opportunities for uninsured and underinsured women to receive PAP screening and HPV testing services, and the most-cited barrier to healthcare is financial concerns.

Intervention Strategies

Working in the Rio Grande Valley and seeing the need for cervical cancer prevention services is what motivated Dr. Rodriguez to start her project, which combines behavioral interventions with both environmental strategies and informational strategies. Behavioral interventions involve reminders such as phone calls or postcards to eligible individuals and to aid in supporting parents' decisions to vaccinate (Rodriguez et al. 592).

> *"We have one person, he's just in charge of the reminders, sending reminders to parents, calling them so we do a lot [. . .] with them. I mean like all kinds of reminders, all kinds of phone calls. We do a lot of work for them to complete the vaccine series."*
>
> *-Dr. Rodriguez*

Environmental strategies increase the number of places where patients can be vaccinated, in this context it involves using the school as an alternative vaccination location (Rodriguez et al. 593). Finally, informational strategies are aimed at educating people about the HPV vaccine (Rodriguez et al. 599). Informational strategies towards increasing HPV vaccination rates involve education on the importance and safety of the vaccine, as well as information about cancers that are associated with HPV (Rodriguez et al. 599).

Before carrying out her school-based program, Dr. Rodriguez conducted a meta-analysis of existing interventions aimed at increasing HPV vaccination rates. The benefit of behavioral interventions varied widely by study: increasing vaccination rates in seven studies and having a small or no effect in five studies (Rodriguez et al. 596). One study used an immunization database to target eligible children, and sent families postcards reminding them about the HPV vaccination, resulting in increases in first-dose vaccination rates for both boys (increase from 14% to 32%) and girls (increase from 27% to 43%) aged 11-12 when compared to a control group; however, the same increases were not seen in girls aged 13-18 (Rodriguez et al. 595). Another study in the meta-analysis found informational strategies to be beneficial; including phone calls, letter reminders, and home visits significantly increased HPV vaccine initiation (from 43% to 59%) and completion rates (24% to 37%) among girls aged 11-15 years old when compared to a control group that only had telephone reminders (Rodriguez et al. 595). The meta-analysis also found that purely educational interventions had a mixed benefit, but the combination of behavioral and educational interventions doubled HPV vaccine initiation (Rodriguez et al. 596). The meta-analysis also confirmed that school-based vaccination programs were successful at increasing HPV vaccination rates (Rodriguez et al. 596). One vaccination clinic in a Denver school resulted in 70% of non-vaccinated students starting the HPV sequence (Rodriguez et al. 596). Further, 88% of students that started the vaccine sequence through the school-based clinic completed it, resulting in a 62% completion rate overall (Rodriguez et al. 596).

Dr. Rodriguez first started a school-based vaccination program in Starr County in 2016 and has since gained additional funding from the Cancer Prevention and Research Institute of Texas (CPRIT) to expand to Hidalgo County in 2019 (*PP190023 — Cancer Prevention and*

Research Institute of Texas). Prior to Dr. Rodriguez's school-based vaccination project, HPV vaccination rates in Starr County were low when compared to the rest of the state: 27.9%-35.8% for females and 21.1%-29.9% for males aged 9-18 (*PP160097 — Cancer Prevention and Research Institute of Texas*).

Structure

At the beginning of her project, Dr. Rodriguez focused on education. Dr. Rodriguez regularly hosts presentations from experts in cervical cancer and HPV immunizations (Rodriguez). The presentations are targeted towards parents, school nurses and staff, and healthcare providers in the community (Kaul et al. 1). The experts present on the importance of the HPV vaccine, the cancers it can prevent, safety, rates of cervical cancer in the Rio Grande Valley, as well as other topics (Rodriguez). These presentations are often conducted in Spanish, as many parents in the Rio Grande Valley speak Spanish at home (Rodriguez). The presentations were coupled with educational materials about the HPV vaccine created by the Center for Disease Control and Prevention (Kaul et al. 1).

> *"I have a pediatrician that is an expert worldwide in vaccines [and] comes with me, he talks to the parents. I also have colleagues from MD Anderson that are very famous and well-known for their work in HPV and cervical cancer. That's the unique part of my program is that the actual physicians come to talk to the parents."*
>
> *-Dr. Rodriguez*

Dr. Rodriguez also partners with local schools to set up vaccination events. She advertises the event on school Facebook pages along with radio advertisements and flyers (Rodriguez). Prior to the event, the school nurses compile forms with children's missing

vaccinations and send them home to parents with a consent form attached (Rodriguez). Notably, the form does not separate vaccines that are required for enrollment in public schools, like Tdap, from the HPV vaccine (Rodriguez). Parents see a list of vaccines that their children do not have and sign the form, sending it back to school with their child to turn in (Rodriguez). On the day of the vaccination event, children are pulled out of class to receive their vaccinations.

At the clinic, children are able to receive many mandatory school vaccines, as well as seasonal flu and HPV vaccines. A contracted company delivers the vaccines, and then Dr. Rodriguez's team is able to update the children's vaccination records (Rodriguez). The clinics run throughout the school day and extend to after school, and anyone in the school district is welcome to come. If children are vaccinated outside of their school, the updated vaccination records are faxed to the school nurses at the appropriate school. Additionally, parents are welcome to come to the school to be with their children when they are vaccinated if they wish (Rodriguez).

A defining feature of Dr. Rodriguez's project is that her vaccination events are often coupled with other events (e.g., PTA and back to school nights) with high parent turnout. For example, I attended an HPV vaccine presentation from Dr. Jane Montealegre, a behavioral epidemiologist at MD Anderson, in McAllen that was held after a parent meeting on upcoming standardized testing in a school cafeteria. Because parents were already attending a presentation at the school, Dr. Rodriguez bundled her presentation so that there would be higher turnout. After Dr. Montealegre's presentation, Dr. Rodriguez and her team stayed at the school to answer any additional questions that parents have. Hosting a one-on-one conversation between an expert and a parent also helped to create a community champion. The parent that asked questions about the safety of the vaccine remarked that she was involved in the parent-teacher-association at the

school and would spread information about the vaccination event to other parents. Targeting and educating influential parents could help to create a community norm of vaccination. If these parents are advocating in the community, it may encourage other parents to also vaccinate their children. In addition, they also set up vaccination events during popular school events, such as "Back to School Nights." In this approach, she takes advantage of high parent turnout to reach as many parents at once as possible. She also tries to time clinics so that children that are vaccinated with the first dose of the HPV vaccine can get additional doses at other school-based clinic days.

> *"[The school-based] location is very key because we do both things: we offer the vaccine, we increase access but we also increase the awareness and the education among parents, stakeholders in the community, [and] the school board members so [. . .] we involve a lot of people in this."*
>
> *-Dr. Rodriguez*

Additionally, if parents are not comfortable vaccinating in a school-based setting, Dr. Rodriguez partners with providers in the community to aid in increasing vaccination rates in doctors' offices as well through referrals. Before starting her project, Dr. Rodriguez was concerned that providers in the community may object to school-based vaccination. If healthcare providers are struggling financially to keep their offices open, missing out on revenue from vaccination may be problematic. Additionally, taking business away from local providers may make healthcare access problems worse if it causes clinics to close. However, Dr. Rodriguez has not found this to be the case. Healthcare providers have expressed that the money needed to stock and supply vaccines makes vaccinations not very profitable. Therefore, her financial impact on local providers is likely not substantial. Additionally, it is possible that by offering

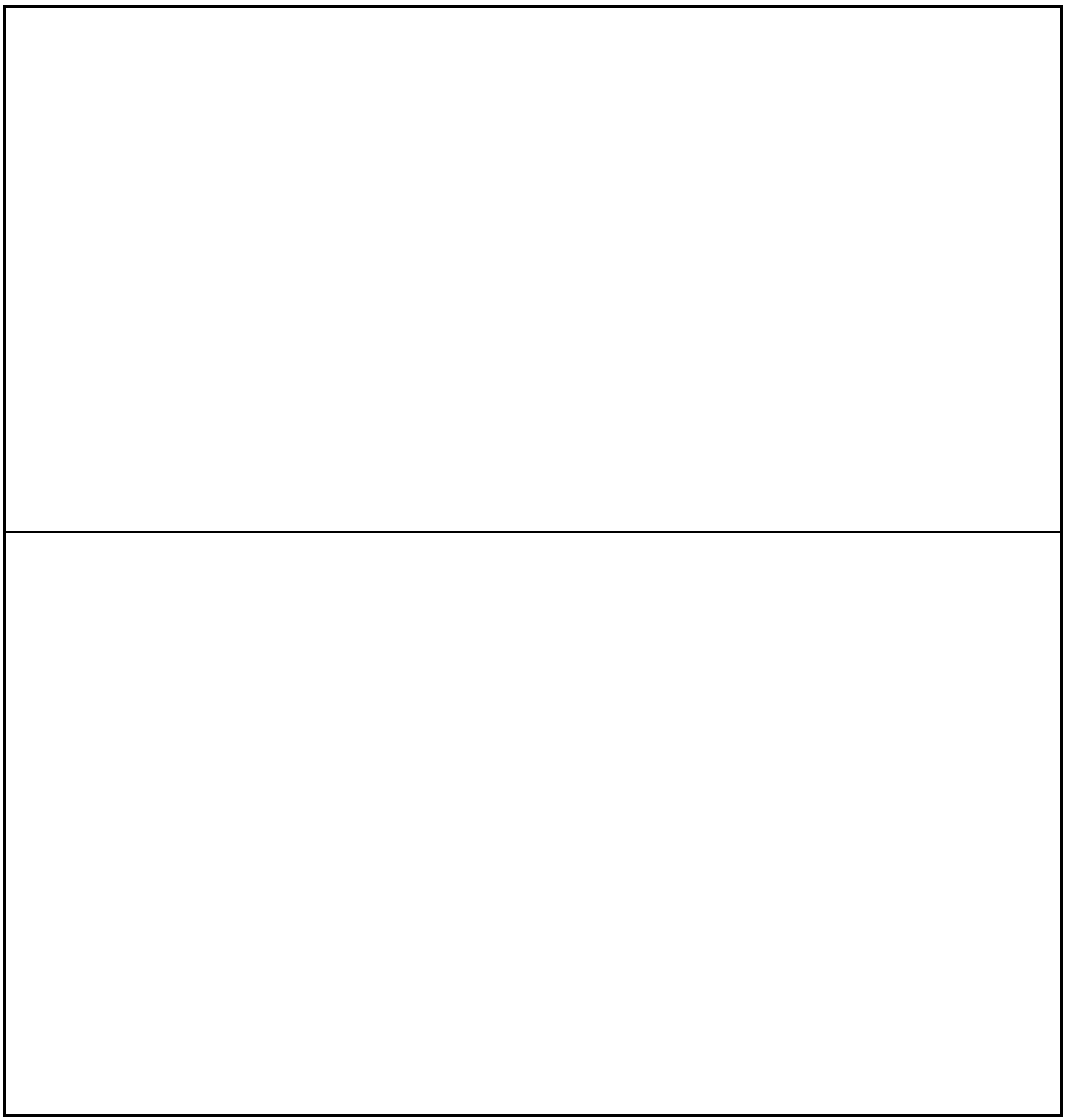
simple immunizations in a school-based setting allows for more available appointments for timely access to healthcare, especially for other services that may be more profitable for clinics.

Results

Dr. Rodriguez recently published the preliminary results of her school-based vaccine program in the Rio Grande Valley. The aim of the study was to compare an intervention school that received community-based education and school-based vaccination to two control schools that only received community-based education (comparison schools). The education included both events and educational materials and was the same between the three schools (Kaul et al. 4). Both the intervention school and control schools were in the same medically underserved, rural area in the Rio Grande Valley (Kaul et al. 1).

Prior to the education and vaccination interventions, the intervention school had lower rates of HPV vaccine completion when compared to the two control schools (see figure 6) (Kaul et al. 1). After the program, the intervention school that received an HPV vaccine education and school-based vaccination had higher rates of HPV vaccine initiation and completion than the control schools that only received the education (see figure 6) (Kaul et al. 4). Overall, children enrolled at the school with both intervention strategies were nearly four times more likely to initiate and complete the vaccine sequence than children at schools with no HPV vaccine interventions (Kaul et al. 4).

Figure 6 HPV Vaccination Rates for Intervention and Comparison Schools (Kaul et al. 4).



Case Study 2: Dr. Paula Cuccaro, School-Based Vaccination in Houston

"Our focus [. . .] is on increasing access to vaccinations, which includes offering free vaccines at a time and place that is convenient to the parents."

-Efrat Gabay, Project Coordinator

The goal of Dr. Paula Cuccaro's program is to increase access to free vaccines at a time that is convenient to parents. Her school-based vaccination program is currently running in nearly 30 public schools in the Houston area (Cuccaro and Gabay). The Houston area/Harris County has 19 designated medically underserved areas ("MUA Find"). These areas are identified as having high poverty rates, infant mortality rates, a large elderly population, and/or a shortage of primary care physicians ("MUA Find"). Most of the schools that Dr. Cuccaro's project operates in are medically underserved and have predominantly minority populations (Cuccaro and Gabay).

Structure

Dr. Cuccaro's intervention involves three parts: a marketing campaign on social media that targets parents, school-based vaccination in middle schools, and education opportunities for school nurses so that they can become advocates for the HPV vaccine (Cuccaro and Gabay). She partners with two contractors to deliver the vaccine, one of which is the Texas Children's Hospital Mobile Clinic Program (Meus). The other partner that delivers vaccines is an on-campus vaccine partner that the schools have existing relationships with.

> *"Each student in the school regardless of their immunization status receives a packet which includes a cover letter in both English and Spanish where we explain to the parents, why we're doing this immunization clinic, that it's free and what the forms are that they need to complete."*
>
> *-Efrat Gabay, Project Coordinator*

About a month before the vaccination clinic, Dr. Cuccaro's team sends consent materials home with the children. Rather than send out consent forms with other paperwork at the

beginning of the school year, they must send the forms home 30 days before the vaccination event because the forms are only valid for a month per the vaccine provider's policy (Cuccaro and Gabay). Bilingual information about the HPV vaccine, including its importance and safety, is sent out along with the consent form packets. Additionally, postcards are sent to homes as a reminder to attend the vaccination event, and there are also advertisements on various digital platforms.

On the day of the vaccination clinic, Dr. Cuccaro's staff goes to the school to check forms for completion and also see if there are children missing vaccines that parents did not consent to. Then, they are able to provide personalized education to parents in an attempt to get consent for missing vaccinations (Cuccaro and Gabay). Then, Dr. Cuccaro has a copy of the children's schedules and her team tries to pull them out of class for vaccination at the least disruptive time possible.

One defining feature of Dr. Cuccaro's work is that they use targeted advertising on social media. Dr. Rodriguez's team creates posts in school Facebook pages, but Dr. Cuccaro also purchases ads on Instagram, Facebook, and Spotify that target people in area codes near the schools where vaccination clinics will take place (Cuccaro and Gabay).

> *"[We have] a call to action Facebook ad [. . .] so like two days or so after that content materials are distributed at the schools, parents may see these targeted ads [. . .] by their zip code, saying, 'Hey, check your child's backpack [for a vaccine consent form].'"*
>
> *-Efrat Gabay, Project Coordinator*

Another feature that makes Dr. Cuccaro's project different from Dr. Rodriguez's project is that Dr. Cuccaro offers services for members of the community as well on vaccination days. In

addition to vaccinating on the school campus, they also have a mobile clinic van outside in the community.

A current barrier that Dr. Cuccaro is trying to navigate are her contractor's policies on insurance. She originally planned to offer vaccines for all children in the participating schools that needed vaccines. After she obtained funding for her intervention, she found out that the vaccine provider that she was using does not accept the Children's Health Insurance Plan or private insurance (Cuccaro and Gabay). She is in the process of trying to overcome this barrier through working with other vaccine providers in order to expand her intervention's reach (Cuccaro and Gabay).

Results

In results provided by Dr. Cuccaro and her team, they distributed 24,000 packets to students in participating schools. Very few of these students returned consent packets and even fewer participated in the clinic. In addition to unreturned forms, other reasons for non-participation include that the student was absent on the day of the clinic, they were not eligible for the Vaccines for Children program, or children were already up-to-date on their vaccines and therefore had no need for the program (Cuccaro and Gabay). Program uptake can be seen in the chart below. (Note: three vaccination clinics were canceled in Year 3 due to coronavirus concerns, so these numbers are lower than expected).

Table 7 Dr. Cuccaro's Program Uptake (Cuccaro and Gabay)

Program Year	Children that Received Any Vaccine	Children that Received HPV Vaccine	HPV Vaccine Refusal Rate

Year 1	773	599	4.9%
Year 2	883	691	2.5%
Year 3	751	514	3.8%
Total	2347	1864	-

Not every student that received vaccinations received the HPV vaccine. In most cases, this was because these children were often up-to-date on their HPV vaccines, rather than parent refusal (Cuccaro). The HPV vaccine refusal rates were low overall (see table 7). This indicates that parents do not appear to be more hesitant to vaccinate for HPV compared to other immunizations.

Additionally, Dr. Cuccaro's program saw an increase in HPV vaccine initiation and completion rates of 10.4% and 8.8%, respectively during the first year (Cuccaro). Data for the other two years was not yet available at the time of this thesis. When these initiation and completion rates are compared to Dr. Rodriguez's program, the percentage increases of Dr. Cuccaro's program are much lower (figure 6). However, the baseline HPV vaccine initiation and completion rates were not given for Dr. Cuccaro's project, so it is difficult to do much comparison between the rates.

Comparing Program Barriers

When comparing the programs, I will primarily consider the barriers they faced and how they overcame them. Notable barriers include missing or incomplete shot records, unreturned consent forms, and staff turnover.

A key theme from my interview with Dr. Cuccaro were the barriers to vaccine provision. One of the most important barriers was missing shot records (Cuccaro and Gabay). In the schools

that her program serves, the student population is relatively transient (Cuccaro and Gabay). While public schools require vaccination records, students that are new to the school may not yet have a vaccination record on file. Additionally, she has observed various rates of enforcement of this requirement in schools (Cuccaro and Gabay).

Both Dr. Rodriguez and Dr. Cuccaro mentioned unreturned consent forms as a barrier to vaccination. The vaccine information and consent forms travel home with students and must be signed by parents and returned in order for children to participate in the vaccination program. Both teams spend a lot of time trying to follow-up on unreturned forms for children that need vaccines. Dr. Cuccaro uses targeted ads to reach parents within a certain geographic area and urge them to check their child's backpack for a consent form to fill out (Cuccaro and Gabay).

Another barrier that is common to Dr. Rodriguez and Dr. Cuccaro's programs is that their programs can be greatly impacted by staff turnover within schools. The school nurses in both programs are responsible for compiling vaccination records, and new nurses may not be as familiar with the software required to do so. Additionally, the programs need approval from principals and superintendents. When leadership turnover occurs, Dr. Rodriguez and Dr. Cuccaro must work to convince them that the programs are worth supporting. They both do so through explaining the benefits of the program and its proven successes. As the programs become more established, this will likely become easier to do. The results will speak for themselves and market the program to new schools in addition to maintaining the old.

Key Takeaways

Dr. Cuccaro's intervention is similar to Dr. Rodriguez's project in the Rio Grande Valley: she couples education geared towards parents and healthcare providers along with

comprehensive vaccination in schools. Both programs have been able to successfully increase HPV vaccination rates. A notable trend that emerged in my research is the ability for school nurses to have a major impact on school-based vaccination. In Dr. Rodriguez's program, a school nurse created a new version of the missing vaccine form that presented the HPV vaccine along with the other vaccines. It was not singled out as an "optional" vaccine next to the vaccines that are required in public schools. Listing the HPV vaccine as optional can make it appear unnecessary, but this updated form will help parents understand the vaccine's importance.

In contrast, in an interview with Dr. Cuccaro, she shared an anecdote of challenges that she faced with nurse turnover. They had worked with the previous nurse to run the program, and now the new nurse had to learn how to help with the vaccination clinic in addition to adjust to her new position. Ultimately, my research highlighted the crucial role of nurse support and cooperation in school-based vaccination clinics.

Dr. Rodriguez and Dr. Cuccaro were both able to successfully implement school-based vaccination clinics. In the case of Dr. Rodriguez's intervention, her results still are not high enough to reach Healthy People 2020 goals ("2020 Topics & Objectives: Immunization and Infectious Diseases"). (Note: Dr. Cuccaro did not provide changes in HPV vaccine initiation and completion rates). Australia has used school-based vaccination programs to achieve very high vaccination rates: 88.9% for dose 1, 86.0% for dose 2, and 80.2% for dose 3 in 2017 ("Historical Human Papillomavirus (HPV) Immunisation Coverage Rates"). In the next chapter, I will examine the structure of Australia's school-based vaccination program to suggest solutions to the barriers faced by school-based vaccination programs in Texas.

Chapter 5: Implications/Recommendations

Texas and Australia

School-based vaccination has already been successful in Australia. Their government-run program has achieved high HPV vaccination initiation and completion rates ("Historical Human Papillomavirus (HPV) Immunisation Coverage Rates"). In contrast, Texas' HPV vaccination rates are much lower. There are major differences between Australia and Texas in regard to vaccination that may contribute to differences in vaccination rates. These include Australia's Medicare system, accessible immunization tracking, and rich history of school-based vaccination. Regardless, there are some similarities that may make Australia a good model for Texas.

First, Texas and Australia have a similar population size. As of 2019, Australia had an estimated population of around 25 million, while Texas estimates were nearly 29 million ("Australian Demographic Statistics, Sep 2019")(*U.S. Census Bureau QuickFacts*). Second, HPV vaccination is not required for public school entry in both Australia and Texas. (note: as of 2016, conscientious vaccine objectors may not be eligible for certain tax benefits (Baidawi). Examining Australia's successful school-based HPV vaccination program can help to identify areas for improvement in current HPV vaccination programs in Texas.

Immunization Tracking: Australia and Texas

Vaccine tracking is crucial to the success of school-based vaccination. In many school-based vaccination clinics in Texas, school nurses are responsible for assembling vaccination records and consent forms that reflect vaccines that students are missing (Rodriguez). Because of this, school-based clinic interventions rely on having access to accurate vaccination records. For

example, when nurses are given paper copies of immunization records, they must manually upload them into their records. In contrast, if students are enrolled in ImmTrac2, nurses can easily access digital copies of their immunization records ("ImmTrac Texas Immunization Registry"). This makes it easier to compile the forms needed for school-based vaccination. Existing tracking software in Texas could be optimized to facilitate school-based vaccination programs through implementing lessons learned from Australia's Immunisation Register. Improving vaccination records will also help avoid roadblocks that arise due to students not having vaccination records that Dr. Cuccaro found in her interventions (i.e. due to transient student populations) (Cuccaro).

Australia is able to track vaccination through the Australian Immunisation Register which includes vaccines that were given as a part of the National Immunisation Program, given in schools, and privately funded vaccines such as vaccines for travel (*Australian Immunisation Register - Services Australia*). The system is run by the Australian government and used by all states and territories. In the United States, many states have their own vaccine-tracking system, and some even have multiple tracking systems within a single state ("Contacts for IIS Immunization Records"). This can cause difficulties when people move between states. There is no automatic way to transmit vaccination records, and it must be requested and then added to another state's vaccination record.

In an ideal vaccination tracking system in the United States, there would be better communication between states. This would result in better transferring of records when people move states. The more immunizations that are recorded in immunization tracking systems, the easier it is to compile consent forms for school-based vaccination. One solution could be a federally created general database that states can modify to suit their individual needs. For

example, states could customize their systems to be able to send reminders about required vaccines in their states. Alternatively, existing state immunization tracking systems could be modified to share information between them. Both of these solutions would improve communication between states and instant access to vaccination records even when people move across state lines.

In Australia, the Immunisation Register is much more compatible with EHRs than ImmTrac2. The Australian Department of Human Services sends practice software vendors updates so that they can sync their data with the Australian Immunisation Register ("Using the Australian Immunisation Register"). In Texas, some EMRs can automatically send vaccination records to Immtrac2. However, vaccine records taken from Immtrac2 must be manually entered in EHRs ("Report on the State of the State December 2018" 51). The systems do not have bi-directional communication. While healthcare providers are required to report all vaccinations given to people under the age of 18, it may be less likely for vaccines to be recorded if it takes extra unpaid time to report them.

Once vaccinations are recorded in the Australian Immunisation Register, they can be accessed by parents through a login associated with their Medicare account. The records can be downloaded and emailed to entities that require them, like some daycare centers ("Using the Australian Immunisation Register"). In Texas, parents are given the choice to opt in to ImmTrac2 at their child's birth, and only 5% of parents decide to opt-out (J. A. Boom, Sahni, et al., "Immunization Information System Opt-In Consent" E23). However, parents and guardians cannot login to ImmTrac2 to see their child's vaccination status. In order to receive a copy of their child's immunization record they must contact an entity that has access to the system, such as a healthcare provider. There is no US government-run way for the general public access

vaccination records online ("Immunization Records for Child Care, School, Athletic Teams, Summer Camps, and Travel"). The Australian system can also send reminders for vaccinations that are past due, including the HPV vaccine (*Australian Immunisation Register - Services Australia*). Healthcare providers in Texas may send out reminders for due vaccinations but they are unable to notify parents through the ImmTrac2 system ("ImmTrac Texas Immunization Registry").

If parents in Texas could access their children's vaccination records directly through ImmTrac2, all parents could see the vaccines that their children have and need. This is especially true for children without a medical home, where parents may have greater difficulties in accessing immunization records. This, coupled with improved coordination between ImmTrac2 and EHRs would mean that healthcare providers would not have to manually enter information from ImmTrac2 into the specific EMR that their clinic uses ("ImmTrac Texas Immunization Registry"). This would result in less room for human error and overall higher-quality vaccination records. Further, if contact information was put into ImmTrac2, parents could be notified of outstanding vaccines that are recommended or required for entrance into public schools.

Additionally, school nurses could use the system to send notifications about school-based vaccinations at their schools and send reminders to turn in vaccine consent forms. Vaccine reminders would be especially important for the HPV vaccine, as the two doses should be taken at least six months apart (Meites et al. 700). While some healthcare providers may already send out immunization or appointment reminders, a reminder system embedded in ImmTrac2 could help improve HPV vaccination completion rates. Instead of reminders varying by office, a reminder could be sent out to the roughly 95% of people who opt-in to ImmTrac2 (J. A. Boom,

Sahni, et al., "Immunization Information System Opt-In Consent" E23). This system would also be able to reach children that do not have a medical home.

Additionally, if the system could be used to remind parents to turn in consent forms for school-based programs would help reduce the number of forms that never get turned in, which is a current problem in Australia's program as well as in Dr. Cuccaro and Dr Rodriguez's interventions (Garland et al. S30). Another way that ImmTrac2 could be optimized to support school-based vaccination is through adding the capability to store consent forms. If ImmTrac2 was configured so that parents could electronically sign the consent forms and upload them through the portal, then more students would be able to be vaccinated. There would be fewer cases of students forgetting to bring forms home and then back to school, possibly increasing HPV vaccination rates through school-based programs.

Further, if parents had access to their children's vaccination records, it may make the records more accurate. In 2018, The Immunization Partnership reported that 54% of vaccine stakeholders found ImmTrac2 records to be incomplete ("Report on the State of the State December 2018" 51). If vaccine providers either did not input vaccines into ImmTrac2 or made a mistake when submitting them, parents may be able to identify mistakes. Especially if parents were notified when ImmTrac2 records were updated, they could certify that the records were correct to the best of their knowledge.

While these proposed changes could have a large positive impact on the success of school-based vaccination programs and vaccination rates overall, it should be noted that these are large changes that will require government intervention. Some of these changes could be implemented in the long-term; however, they are unlikely to become reality in the near future as they rely on large restructuring of the government/government programs. For example, allowing

for parents to log in to ImmTrac2 would require a large investment into the software to ensure that the system can support many more people logging in at the same time and also maintain patient privacy.

Vaccine Affordability

In Australia, all vaccines that are a part of the National Immunisation Program Schedule are provided to children, seniors, and certain at-risk populations for free under their single-payer Medicare system (*How to Enrol and Get Started in Medicare - Enrolling in Medicare - Services Australia*). Children have received the HPV vaccine for free in school settings since the addition of the HPV vaccine to the National Immunisation Program Schedule in 2007 ("History of Immunisation in Australia"). Medicare covers all Australian and New Zealand citizens, as well as permanent residents (*How to Enrol and Get Started in Medicare - Enrolling in Medicare - Services Australia*).

Texas has a similar program that provides low-cost vaccines to children: Texas Vaccines for Children; however, only some children qualify. This includes uninsured or underinsured children, CHIP recipients (low-cost health insurance children who are low-income but who do not qualify for Medicaid), children on Medicaid, and children who are Native American or Native Alaskan (*Information for Providers - Texas Vaccines for Children*). Further, Texas Vaccines for Children covers the cost of the vaccine, but patients can still be charged a vaccine administration fee (*Information for Providers - Texas Vaccines for Children*). While this fee is small, it could be a barrier to vaccination for poor families. This means that vaccination programs must take private insurance, as well as the Texas Vaccines for Children program (Cuccaro and Gabay). School-based vaccination clinics must navigate billing for different kinds

of insurance, which can cause additional problems. For example, Dr. Cuccaro's vaccine provider does not take CHIP or private insurance, meaning that some children at participating schools may not be eligible for her program.

The problems that arise from taking multiple insurance formats are not likely to be solved under the current American healthcare system. It is a variable that must be considered when comparing the Australian school-based vaccination programs to Texas. While there are programs that make vaccines more affordable, they make vaccine reimbursement more complicated. Unless the United States has a major change in its healthcare structure, this problem will continue to exist.

Texas's Lack of Vaccine Infrastructure

Australia already had school-based vaccinations in all states and territories prior to the addition of the HPV vaccine to the National Immunisation Program (Ward et al. E169). This meant that the infrastructure was already in place to deliver the HPV vaccine in a school-based setting. In addition, the Commonwealth of Australia funds the vaccines through Medicare, and then local health departments fund the clinics at schools (Dey et al. 18).

In contrast, School-based vaccination programs in Texas must navigate funding, consent forms, and vaccine education without direct support of the government (besides access to state-level immunization tracking). Dr. Cuccaro and Dr. Rodriguez must rely on partnerships with school nurses in order to access immunization records, send home consent forms, and schedule clinics. They are working on the level of small numbers of schools at a time rather than on a statewide or even citywide level. As a consequence, turnover has a major impact on their operations. New nurses may not be comfortable operating immunization software, and turnover

education may be difficult. Additionally, new principals or superintendents may be skeptical about school-based vaccination programs if they transfer from schools and districts that do not have them, or their personal attitudes and beliefs may act as a barrier to implementing school-based vaccination.

These problems will likely be less of an issue as Texas programs continue to be established. In an interview, Dr. Cuccaro mentioned that when there is a new superintendent or principal, they point to the successes of previous programs to establish legitimacy. Their success rates make their program desirable, and school leaders tend to support them. As the programs become more optimized, they will likely become easier to implement.

The Role of Education in School-Based Vaccination

On the parent level, Australian and Texan school-based vaccination programs both include an education component. Australia also has a video series geared toward high school students that explains what to expect during a school-based vaccination clinic in addition to information about the vaccine ("Vaccination Videos for High School Students").

Both Dr. Cuccaro and Dr. Rodriguez's programs include targeted education in addition to sending home vaccine information along with the consent forms. Dr. Cuccaro has created a targeted intervention to increase HPV vaccination within the school-based clinic. She sends postcards to students' homes with reminders to attend the clinic and return consent forms. She also uses social media platforms to run targeted ads in areas near the participating schools with reminders about the vaccination form. For example, posting on the school's parent Facebook group page could be a way to reach many parents at once. Posting about upcoming vaccination events and reminders to turn in consent forms could help increase consent form yield. Recruiting

involved parents to serve as community champions, like Dr. Rodriguez does in her programs, could also help publicize vaccination events and create a social norm of vaccination. These interventions educate parents on the benefits of the vaccine and remind them to submit consent materials.

Dr. Rodriguez's program uses the school website to publicize upcoming vaccination clinics and invites expert speakers to present at participating schools. These speakers include cancer researchers and epidemiologists that explain how the vaccine works to parents. From my experience observing Dr. Rodriguez's presentations in McAllen, the presenters aimed to make their presentation accessible and easy to understand. They also stayed after the presentation to answer parents' questions about the HPV vaccine and address their concerns. They hold these presentations as standalone events as well as a part of outside programming. For example, they may give quick presentations at "back-to-school nights," so that they take advantage of events at the school that parents already attend to broaden their reach. Both of these educational approaches may help bridge the "vaccine intention-behavior gap," where parents want to vaccinate but do not do so immediately because they want more information or face other barriers to vaccination (Auslander et al. S27).

While these programs educate parents about the vaccine, they do not explain the specifics of school-based vaccination. Additionally, while some students may attend the presentations that Dr. Rodriguez's program hosts, the students are not the focus. Australia's educational video series specifically targets students and educates them about the importance of the vaccine. This may lead students to be more comfortable with the idea of receiving vaccines in a school-based setting.

Providing educational programming for both children and parents may also aid in addressing the stigma around sexually-transmitted-infections in relation to the HPV vaccine. Some healthcare providers are hesitant to discuss the HPV vaccine with children at the recommended vaccination age of 11 because they are uncomfortable talking about sexually-transmitted-infections with young children (Madhivanan et al.). Parents may also share these same hesitations. Providing education to parents and children could help to provoke an age-appropriate discussion of the benefits of the HPV vaccination and increase vaccination rates.

Conclusion and Future Research

Dr. Rodriguez's program has already shown its ability to raise HPV vaccination rates (Kaul et al. 5). In order to come closer to Healthy People 2020 goals, changes must be undertaken to optimize school-based vaccination programs. Many of these changes can be lessons learned from Australia. Larger changes, such as modifications to ImmTrac2, would make school-based vaccination in Texas easier to implement, but these changes would be more difficult than school-based approaches. Targeted social media marketing, consent forms that list the HPV vaccine alongside required vaccines, reminders, community champions, and increased educational programming, such as videos have the potential to aid in the success of future school-based HPV clinics in Texas.

Areas of future research include looking into how improvements to existing school-based HPV programs could be the most viable. In regard to immunization tracking software in Texas, could ImmTrac2 be equipped to store consent forms and/or send reminders to parents about due vaccinations and upcoming school-based vaccination programs? For future educational/informational interventions, would educational videos like those in Australia's

school-based HPV vaccination program be more or less effective than existing interventions in Texas? Ultimately, more research is needed to hone lessons-learned from Australia's school-based HPV vaccination program into a targeted intervention fit for Texas.

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